# EPA Registration No. 66171-7 Vol. 4



World Headquarters P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

California Operation 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

August 31, 2011

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

1 Addition of the following Salmonella enterica serotypes:

Salmonella Enteritidis Salmonella Choleraesuis Salmonella Dublin • Salmonella Heidelberg • Salmonella Paratyphi Salmonella Typhi Salmonella Typhimurium Salmonella Pullorum Salmonella Gallinarum Salmonella Brandenburg •

We have included the required: 1) USEPA Form 8570-1, Application for Pesticide, 2) Formulator's Exemption for both active ingredients, 3) Certification with respect to citation of data, 4) Data matrix, 5) six copies of the proposed labeling and 6) three copies of the confirmatory data.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President

48594401 AOAC Use - Dilution Test Method

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm. soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vlnyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles

#### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the ed above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain for at least 10 minutes.
- e buildings, and other closed spaces. Do not house swine or other livestock nent has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



## SYNERGIZE

#### **CLEANER-DISINFECTANT**

STAPHYLOCIDAL · PSEUDOMONACIDAL SALMONELLACIDAL · VIRUCIDAL\* · PARVOCIDAL · FUNGICIDAL **ASPERGILLOCIDAL** 



Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

#### Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C16 1%) dimethyl benzyl ammonium chloride.....26.00% Glutaraldehyde. ...7.00% Inert Ingredients:. .67.00% TOTAL. ..100.00%

#### KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

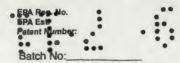
See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied
- or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water,
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.

  7) Thoroughly solub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment whick may come an entact with food with soap or detergent, and rinse with potable water before reuse.



66171-7 66171-TN-001, 66171-CA-001 5,891,922

**Net Contents:** 

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip It back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestig

KEEP OUT OF REACH OF CHILDREN. Corrosive. Caus skin burns. May be fatal if inhaled. Harmful if swallowed get in eyes, on skin or on clothing. Do not breathe spray Wear a dust/mist/filtering respirator (MSHA/NIOSH appr NIOSH approved respirator with any N, P, R, or HE prej rubber gloves. Prolonged or frequent repeated skin cou some individuals. Wash hands before eating, drinking, the toilet. Remove contaminated clothing and wash be

**ENVIRONMENTAL HAZARDS:** This product is to ters, and shrimp. Do not apply directly to water. De equipment or disposal of wastes. Do not discha lakes, streams, ponds, estuaries, oceans or ot requirements of a National Pollutant Discharge the permitting authority has been notified in writing effluent containing this product to sewer system sewage treatment plant authority. For guidance gional Office of the EPA.

#### FIRST

IF IN EYES: Hold eye open and rinse slowl remove contact lenses, if present, after the fir a poison control center or doctor for treatmer IF ON SKIN OR CLOTHING: Take off cont with plenty of water for 15-20 minutes; call ment advice.

IF INHALED: Move person to fresh air. If p lance, then give artificial respiration, prefer poison control center or doctor for further tri IF SWALLOWED: Call a poison control c advice; have person sip a glass of water if a told to do so by the poison control center of unconscious person.

HOT LINE NUMBER: Have the product of control center or doctor, or going for trei for emergency medical treatment infor health concerns, medical emerge Telecommunications Network

NOTE TO PHYSICIA

lavage. Meas be need

Reno, NV 89511 · (800) 995-1607 · www.preserveinternational.com Page 1 of 2



#### HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

#### A) HATCHERY ROOMS

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

#### B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hetchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

#### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc.

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc.

After the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle.

After twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

#### AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### Intermittent (Slug Dose) Method:

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

#### Continuous Feed Method:

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREED-ING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, Instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for gallot readed feed racks, automatic feeders, waterers, all other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other experiment and the experiment of the properties of the following and other experiment and the experiment of the following and oth

Staphylococcus aureus A.T.C.C. 6538

Pseudomonas aeruginosa A.T.C.C. 15442

Salmonella enterica A.T.C.C. 10708

Aspergillus fumigatus A.T.C.C. 36607

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*

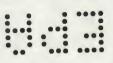
Avian Influenza (H3N2)\*

Escherichia Coli F18

Porcine circovirus Type 2\*

Canine paryovirus A.T.C.C. VR-2016\*

Salmonella Choleraesuis
Salmonella Dublin
Salmonella Enteritidis
Salmonella Heidelberg
Salmonella Paratyphi
Salmonella Typhi
Salmonella Typhimurium
Salmonella Pullorum
Salmonella Gallinarum
Salmonella Brandenburg







Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

#### **DOT SHIPPING NAME**

UN3264, Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, PG III 8/31/11

4



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August 31, 2011

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

1 Addition of the following Salmonella enterica serotypes:

Salmonella Enteritidis
Salmonella Choleraesuis
Salmonella Dublin
Salmonella Heidelberg
Salmonella Paratyphi
Salmonella Typhi
Salmonella Typhimurium
Salmonella Pullorum
Salmonella Gallinarum
Salmonella Brandenburg

We have included the required: 1) USEPA Form 8570-1, Application for Pesticide, 2) Formulator's Exemption for both active ingredients, 3) Certification with respect to citation of data, 4) Data matrix, 5) six copies of the proposed labeling and 6) three copies of the confirmatory data.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President

48594401 AOAC Use - Dilution Test Method

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95 Please read instructions on reverse before completing form **OPP Identifier Number** Registration **United States Amendment Environmental Protection Agency** Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 66171-7 Noble None Restricted 4. Company/Product (Name) SYNERGIZE PM# 31 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) Preserve International (b)(i), my product is similar or identical in composition and labeling PO Box 17003 Reno, NV 89511 EPA Reg. No. Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in repsonse to Agency latter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Addition of Salmonella enterica subsp. enterica serovar Enteritidis to label. Section - III 1. Material This Product Will Be Packaged in: Child-Resistant Packaging **Unit Packaging** Water Soluble Packaging 2. Type of Container Metal Yes Yas Yas Plastic No Glass Paper If "Yes" No. per If "Yes" No. per Certification must Unit Packaging wgt. container Package wgt container Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions 275g,250g,55g,30g,15g,5g,4x1g On Label Label Container Other Sleeve 6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone No. (Include Area Code) 530-879-9220 Title President Gary E. Gaumer 6. Date Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable/law. (Stamped) 2. Signature 3. Title President 4. Typed Name 5. Date

Garv E. Gaumer

August 24, 2011

66171-7 - Synergize (cleaner - Disinfectant) Preserve International

A-570

Not healthcare product, but has public health organismy have confirmatory data

addition of 10 Salmonella enterica sextypes was sent for efficacy review on Sep. 21/201

MRIB 454107 455 485 94401

12.02.2011. Received the efficacy review from Tracy

( Tajah made it) with some label comments

( Tajah made it

Gary Gariner (was sent e-mail on 12,02.11)

12.07.2011. Received a new Label from mr. Gaymir.

1. Look at the Formulator's Exemption and CSES
(agreement with CSES)

cheek 307 subnission for 22 sép 2011 to compare data compensation.

12.09.2012 Data matrix and Formulator's exemption compared. OK,

01.12.2012 Tox Remain (draft by 24.25 january)
01.12.20.12 List the little for letter. 21
02.03. Use dif. template for letter. 20
02.03. Discuss with Tracey. 30'.

paid in fall. Stapt date October 20/2011
Due date Feb. 20/2012. 8 869



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 7, 2011

#### **MEMORANDUM**

SUBJECT:

Efficacy Review for Synergize;

EPA File Symbol 66171-7;

Di

DP Barcode: D394286

FROM:

Karen Hill, Ph.D.

Microbiologist

**Product Science Branch** 

Antimicrobials Division (7510P)

THRU:

Tajah Blackburn, Ph.D.

Team Leader

**Product Science Branch** 

Antimicrobials Division (7510P)

TO:

Velma Noble RM31/ Tracy Lantz

Regulatory Management Branch I

Antimicrobials Division (7510P)

APPLICANT:

Preserve International

P.O. Box 17003

Reno, NV 89511

#### FORMULATION FROM THE LABEL:

Active Ingredient(s):	% by wt.
Alkyl (C <sub>12</sub> 67%, C <sub>14</sub> 25%, C <sub>18</sub> 7%, C <sub>18</sub> 1%) dimethyl benzyl	
ammonium chloride	26.00%
Glutaraldehyde	7.00%
Inert Ingredients	67.00%
Total	100.00%

#### I BACKGROUND

The product, Synergize, is a registered product (EPA Registration No. 66171-7). The applicant has requested to amend the registration to include disinfectant claims against Salmonella enterica subsp. enterica serovar enteriditis on hard non-porous surfaces for industrial and animal care and processing facilities. The product is specifically intended for industrial use in the following Animal and Poultry Housing Facilities: Hatcheries and Swine Producing Facilities, Turkey Breeder, Fryer, Grow Out, and Layer. It is also intended for use on the following equipment: Feeders, Farrowing Barns, Nurseries, Creep Areas, Hauling Equipment, Dressing Plants, Blocks, Loading Equipment, Chutes, and Waterers. The label claims that the product is effective in hard water (as much as 1000 ppm CaCO<sub>3</sub>) and in the presence of 5% serum. The study was performed at Antimicrobial Test Laboratories 3000 Joe DiMaggio Blvd. Suite #32 Round Rock, Texas 78665.

The data package included a letter from the applicant dated August 31, 2011, the Data Matrix, the proposed label, one efficacy study (MRID No. 485944-01), Statement of No Confidentiality Claims, Good Laboratory Practice Compliance statement, and Quality Assurance statement for referenced study.

#### II USE DIRECTIONS

The product is designed to clean and disinfectant hard non-porous surfaces. The product may be used to treat hard non-porous surfaces including: glass, garbage cans, walls, floors, telephone booths, tables, sinks, and refrigerator exteriors. The proposed label claims it may be used on stainless steel, glass, hard non-porous treated wood, polyvinyl chloride, polypropylene, acrylic, ethylene propylene, tin, vinyl, viton, sealed fiberglass, nitrile, polyurethane, galvanized metal, brass, zinc, tin, glazed ceramic and tile, chrome, and aluminum. Directions on the proposed label provided the following instructions for the use and preparation of the product as a disinfectant:

Apply ½ ounce SYNERGIZE per gallon of water (1:256 dilution). Apply with cloth, sponge, mop, or mechanical coarse spray device, allow surfaces to remain wet for 10 minutes, rinse surfaces with clean water, and allow surfaces to dry.

#### III AGENCY STANDARDS

<u>Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria):</u>

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against specific bacteria with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10<sup>4</sup> microorganisms survived the carrier-drying step.

#### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 485944-01 "AOAC Use — Dilution Test Method," Test Organism: Salmonella enterica subsp. enterica serovar enteriditis (ATCC 13076), for Synergize, by Jason Williams. Study conducted at Antimicrobial Test Laboratories. Study completion date- August 2, 2011. Study Identification No. is GLP1077.

This study was conducted against *Salmonella enterica subsp. enterica serovar enteriditis* (ATCC 13076). Two lots (Lots No. 37817 and 37818) of the product Synergize were tested using the provided Antimicrobial Test Laboratories Protocol No. P1084. The product was diluted as 1 part test substance and 255 parts diluent (1:256 dilution). The product was diluted in 1010ppm AOAC hard water. The test culture was incubated for 48±2 hours (48 hrs. and 28 min. indicated in final report) at 36±1°C. Equine serum was added to the test culture to achieve 5% serum load. The stainless steel penicylinder carriers were submerged in 48±2 hours old suspension of test organism for 15 minutes at room temperature. Following, the carriers were placed on double filter paper-lined Petri dishes and allowed to dry for 38 minutes at 35.4°C. The inoculated carriers were each submerged in 10ml of test substance for 10 minutes at 22.2°C. Afterwards, the carriers were transferred to 10mL of AOAC Modified Letheen Broth. All subcultures were incubated for 48±2 hours at 36±1°C prior to examination of the subcultures for the presence or absence of visible growth. Controls for both product lots included carrier count, sterility, viability, and neutralization confirmation.

#### V RESULTS

Lot No.	Microorganism	Number of Positive Carriers / Number of Carriers	Average CFU/Carrier
37817	Salmonella enterica (ATCC 13076)	0/10	9.03 X 10 <sup>5</sup>
37818	Salmonella enterica (ATCC 13076)	0/10	9.03 X 10 <sup>5</sup>

#### VI CONCLUSIONS

1. The submitted efficacy data <u>support</u> the use of the product, Synergize, as a disinfectant with bactericidal activity against the following microorganism on hard, non-porous surfaces in the presence of a 5% organic soil load and 1000ppm hard water for a 10-minute contact time:

Salmonella enterica subsp. enterica serovar enteriditis (ATCC 13076)

MRID 485944-01

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

#### VI RECOMMENDATIONS

1. The proposed label claims that the product, Synergize, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic serum and hard water for a 10 minute contact time:

Salmonella enterica subsp. enterica serovar Enteriditis

These claims are acceptable as they are supported by the submitted data.

#### Label:

 Please remove claims for the following organisms in the absence of acceptable efficacy data:

Salmonella Dublin
Salmonella Heidelberg
Salmonella paratyphi
Salmonella typhi
Salmonella typhimurium
Salmonella pullorium
Salmonella Gallanarum
Salmonella Brandenburg

The ATCC numbers for Salmonella enterica subsp. enterica serovar enteriditis and E. coli F18 are required on master label or data matrix.

 On page 2 of the proposed label in Section B) Incubators and Hatchers, the statement "disperse the sanitizing solution as a fog" conflicts with earlier language regarding the use as a disinfectant.

## STATES ENVIRONMENTAL PROTECTIO

Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511

Subject:

Synergize

EPA Registration No.: 66171-7 Notification Dated: October 11, 2011 EPA Receipt Date: October 18, 2011



Dear Mr. Gaumer,

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRRA), as amended and PR Notice 98-10.

Notification to correct typographical error and add name of product to directions for use.

Based on a review of the submitted information this notification is acceptable and will be made part of the record for this file. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely.

Product Manager (31).

Regulatory management Branch I. Antimicrobials Division (7510P)

7510P:T.Lantz:11/14/11:66171-7 d notification

		CONCURRENC	es		
SYMBOL 17510P					
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DATE   11 14 11					
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World Headquarters P.O. Box 17003, Reno, NV 89511 ● Bus: (775) 853-9776 ● Fax: (775) 406-3413 ● USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 ● Bus: (901) 272-0031 ● Fax: (901) 726-6446

California Operation 1355 Paulson Road, Turlock, CA 95380 ● Bus: (209) 664-1607 ● Fax: (209) 664-1728

October 11, 2011

?

Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (NOTIFICATION)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

To Whom it May Concern:

Preserve International hereby submits this Synergize label as a final printed label in response to the EPA letter dated September 22, 2011.

Further, Preserve International hereby submits a notification to correct a typo error in omitting a comma, and the changing of the phrase located in the veterinary section of the label.

The comma is located in the environmental hazards section between fish and aquatic organisms.

The phrase we changed is: At ½ ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, SYNERGIZE was found to be effective against Canine Parvovirus. The word SYNERGIZE replaced the words "this product".

For your review, we have highlighted the changes.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,
Preserve International

Gary E. Gaumer
President

<b>\$EPA</b>	United State Environmental Protect Washington, DC	ction Agency	Registr Amend Other		OPP Identifier Number	
	Applica	ation for Pesticide - S	Section 1			
1. Company/Product Number 66171-7	or .	2. EPA Product	Manager	3. Proposed Classification		
4. Company/Product (Name SYNERGIZE	)	PM#	PM#			
5. Name and Address of Ap Preserve Internationa PO Box 17003 Reno, NV 89511		(b)(i), my prod to:	uct is similar or idea	ntical in co	FIFRA Section 3(c)(3) mposition and labeling	
		Section - II				
FINAL LABEL PER 9/22/11	inal page(s) if necessary. (For se	ction I and Section II.)	- Explain below.			
		Section - III	3			
1. Material This Product Wi	Il Be Packaged In:					
Child-Resistant Packaging Yes	Unit Packaging  Yes  No  If "Yes"  Unit Packaging wgt.  No. per Contain			Metal Plastic Glass Paper		
* Certification must be submitted		er Package wgt cont		Other to	Specify)	
* Certification must be submitted 3. Location of Net Contents		Package wgt cont Package wgt cont Package wgt cont Package wgt cont Package wgt cont Package wgt cont	5. Location of L			
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* Certification must be submitted 3. Location of Net Contents	Container	Retail Container 275,250,55,30,4x1,2.5x2	5. Location of L			
* Certification must be submitted  3. Location of Net Contents  Label  6. Manner in Which Lebel is	Container	Retail Container 275,250,55,30,4x1,2.5x2 thograph aper glued enciled	5. Location of L	abel Directio	ons	
* Certification must be submitted 3. Location of Net Contents Label 6. Manner in Which Label is	Container  3 Affixed to Product Lings Page St	Retail Container 275,250,55,30,4x1,2.5x2 thograph aper glued enciled	5. Location of L	abel Direction	application.)	

5. Date

4. Typed Name Gary E. Gaumer

OCTOBER 10, 2011

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities; Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### **DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:**

1) Remove all animals and feed from the premises, vehicles and enclosures, 2) Empty ali troughs, racks, and other feeding and watering appliances. 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls. chutes, and other facilities occupied or traversed by hogs or other animals. 4) Thoroughly clean all surfaces with soap or detergent and rinse with water. 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes. 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1.256. Allow to remain in contect for at least 10 minutes. 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed. set, or dried. 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

1) Do not use in milking stalts, milking parlors, or milk houses. 2) Remove all animals and feed from the premises, vehicles, and enclosures. 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chures, and other actities occupied or traversed by hogs or other animals. 4) Empty all rounds, racks, and other ending and watering appliances. 5) Thoroughly clean all surfaces with seap or detergent and rinse with water. 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



## SYNERGIZE

#### **CLEANER-DISINFECTANT**

STAPHYLOCIDAL · PSEUDOMONACIDAL SALMONELLACIDAL · VIRUCIDAL\*

· PARVOCIDAL · FUNGICIDAL **ASPERGILLOCIDAL** 



Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes, This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

#### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride26.00%
Glutaraldehyde
Inert Ingredients:
TOTAL100.00%

#### KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact

8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with notable water before reuse.

#### **DIRECTIONS FOR USE IN POULTRY HOUSE:**

1) Remove all poultry and feeds from premises, trucks, coops, and crates. 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. 3) Empty all troughs, racks, and other feeding and watering appliances. 4) Thoroughly clean all surfaces with soap or detergent and rinse with water. 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes. 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.	66171-7
EPA Est.	66171-TN-001, 66171-CA-001
Patent Number:	5,891,922

Batch No: Net Contents:

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

PESTICIDE STORAGE: Store away from heat. Do not transfer to another container. Do not reuse employentainer

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of

by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promotiv after emotying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. R this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin, Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to light annualic invertebrates, cysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **FIRST AID**

tF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the lirst 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may

## **SYNERGIZE**

#### HATCHERY ROOMS. INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

#### A) HATCHERY ROOMS:

Remove all animats and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

#### **B) INCUBATORS AND HATCHERS:**

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily, Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

#### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, veal barns, veal bar

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

#### AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product is used in industrial air washers and air washer systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours. SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

Intermittent (Slug Dose) Method: Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved. Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

Continuous Feed Method: Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved. Subsequent Dose: Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water lost to blowdown. Badly fouled systems must be cleaned before treatment is begun.

VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREED-ING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensits, instruments, cages, kennels, stables, stables, and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At ½ ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time! SYNERGIZE was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36807
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*
Avian Influenza (HSN2)\*
Escherichia Coli F18
Porcine circovirus Type 2
Canine parvovirus A.T.C.C. VR2006\*



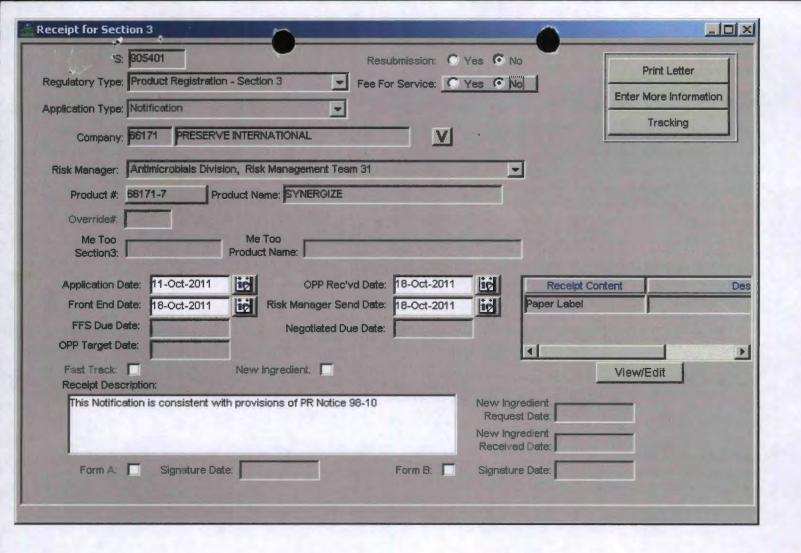
Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

#### **DOT SHIPPING NAME**

UN3264, Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, PG III 10/10/11

## RISK ASSIGNMENT FORM Antimicrobial Division/Regulatory Management Branch I

PRODUCT	DELIENATED.					angele annual traditional place and an arrange and the		
	REVIEWER:	Trau	7			RMBI	TEAM 3	1
Type of A	etion:	Not.	ficat.	ni		12	e Symbol/Reg	No.
Decision	No. 456778	Submission	No. 905	401	Fee fo	r Service A	ction Code:	
FQPA Act	ion Code: 338	Non-FQPA	Action Cod	le:	PR	IA FEE AMO	UNT:	
		MONTH		DAY			YEAR	
APPLICAT	TON DATE	10	11				2011	
EPA PIN D	ATE	10	10 18			2011		
DATE PM F	RECEIVED FROM						2011	
DATE SEN	IT TO SCIENCE							
DATE REC	CEIVED FROM							
DATE DUE	TO PM	Н	1	1		20	11	
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSE Environme Fate		RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/ Residue
1	10t, fica	tor-	6.re	40 7	Tra	ey P	Nout James?	due 2/20/12 2/20/12
ATTACHM	ENTS: -LABEL	ING -	CSF(S)	-DAT	A	-ОТН	IERS	
В			or Arctic S	lope Contra	act Only	/		
Cont	ract No.: 0052	ARCTI	C SLOPE/M	IANAGER				
Final	Task: Signature					(Total hrs	3)	
C Revie	ewer Comments:							
DATE FEE	PAID:		RESPON	ISE CODE:		RESP	ONSE DATE:	187



Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511

Subject:

Synergize

EPA Registration No.: 66171-7 Amendment Date: May 16, 2011 EPA Receipt Date: June 1, 2011



Dear Mr. Gaumer.

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable subject to the comments listed below.

- Addition of Air Washers and Industrial Scrubbing Systems
- Addition of Canine parvovirus

#### Conditions

- 1. Revise the first section on page 2 to begin as follows: "All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging..."
- 2. Make the following corrections to section C) Poultry Houses and Livestock Buildings: add quotation marks after the phrase: ...calf pens and vehicles". Add mandatory language as per PR 2000-5 as follows: "... The Fogger itself is placed just inside... the nozzle of the fogger is inserted..."
- 3. Add mandatory language to the Air Washers and Industrial Scrubbing section as follows: "This product is used in industrial air washers..." "... Addition is made intermittently..." "...Badly fouled systems are shock treated..." "Synergize is used in industrial process water..."
- 4. In the Air Washers and Industrial Scrubbing section, Continuous Feed Method. Subsequent Dose revise to read as follows replacing the first statement with: "Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water last to blowdown Radly fouled systems

	Water rost	. 10 DIOWAOWII	- David Harit	CONCURRENC	ES.		
SYMBOL	7510P						
SURNAME	5 Jank						
DATE	9/22/11						
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EPA Form 1320-1A (1/90)

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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

5. Delete the following incorrect statement from the Veterinary Practice section. This statement is not appropriate as the beginning of this section indicates that the product is not for treatment of equipment used for animal food or water. Delete: "Thoroughly scrub treated feed racks, automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent and rinse with potable water before reuse."

#### **General Comments**

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

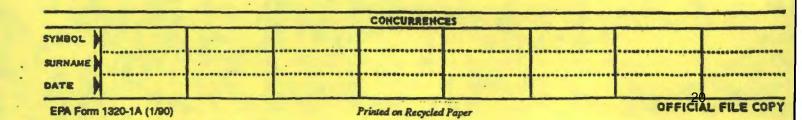
Sincerely.

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

7510P:T.Lantz:9/22/11:66171-7k



#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm. soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcherles and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Murserles, Blocks, Creep Areas, and Chutes. This product is also for use in Farm wine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Pens and associated Farm Vehicles.

#### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gal-Ion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.

oroughly clean all surfaces with soap or detergent and rinse with water. roughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of (1:256), using conventional spraying methods.

6) Allow all treated areas to remain in contact with this solution for at least 10 minutes. 7) Immerse equipment used in handling and restraining animals, forks, shovels, and

scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.

8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### DIRECTIONS FOR USE IN FARM PREMISES, EQUIRE PACILITIES, VEAL BARNS, RATTES FACILITIES, CALF PENS AND VEHICLES:

Page 1 of 2

 Do not use in milking stalls, milking partors, osmills houses
 Remove all animals and feed from the granists, vehicles and enclosures.
 Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of bams, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals

4) Empty all troughs, racio, and other feeding and watering appliances.

5) Thoroughly clean all surfaces with soap or detergent and rins with water 6) Thoroughly saturate all surfaces with a solution of fi2 oz. 5/NIHROZE per gallon of water (1:256), using conventional seraying methods. Allow to remain in contact with this solution for at least 10 miliutes.

**PRESERVE** INTERNATIONAL

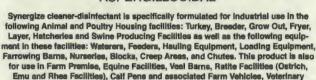


#### CLEANER-DISINFECTANT

STAPHYLOCIDAL · PSEUDOMONACIDAL

SALMONELLACIDAL · VIRUCIDAL\*

· PARVOCIDAL · FUNGICIDAL **ASPERGILLOCIDAL** 



#### Active ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....26.00% Glutaraldehyde Inert Ingredients: .67.00% TOTAL.

Practice, Animal Care, and Animal Laboratory.

#### KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.

8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried,

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### **DIRECTIONS FOR USE IN POULTRY HOUSE:**

1) Remove all poultry and feeds from premises, trucks, coops, and crates,

2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied

or traversed by poultry.

3) Empty all troughs, racks, and other feeding and watering appliances.

4) Thoroughly clean all surfaces with soap or detergent and rinse with water

5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a

6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried,

7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No. EPA Est. **Patent Number:** 

66171-7 with COMMENTS 66171-TN-001, 66171-CA-001 in EPA Letter Dated: 5,891,922

Batch No:

Net Contents:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide,

registered under EPA Reg. No. 66171-7 Reno, NV 89511 · (800) 995-1607 · www.preserveinternational.com

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law, if these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple ringe container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. To container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tio it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gaillons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

DANGER

KEEP OUT OF REACH OF CHILDREN, Corrosive, Causes irreversible eve damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear googles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the tollet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, ovsters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric layage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

21

## **SYNERGIZE**

#### HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

#### A) HATCHERY ROOMS

Nemove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

#### **B) INCUBATORS AND HATCHERS:**

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging vicin into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breather this fog and do not enter machines until the fog has settled (30-80 minutes after fogging is lefted). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per nour or once every two hours.

#### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERIGIZE to 100 fluid ounces SYNERIGIZE to 100 fluid ounces water), Insert the nozzle of the fogging device through in the beating on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger taste fluid ounce water) in the pening in the door of the building. The opening in the door or building. The opening must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened for a minimum of wenty-four (24) hours before the restock.

NOTE: The generated fog is very irritating to eyes, akin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and parts. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

#### AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### Intermittent (Slug Dose) Method:

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 galions of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

#### **Continuous Feed Method:**

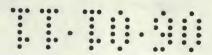
Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

pequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

VETERINARY PRACTICE (CLINICS/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREED-ING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all ilitter, droppings and manure from floors, walls and surfaces of facilities occupied or traverseed by animals. But no for 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as order, and storage and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse. At ½ ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, this product was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36807
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*
Avian Influenza (H3N2)\*
Escherichia Coli F18
Porcine circovirus Type 2\*
Canine parvovirus A.T.C.C. VR-2016\*







Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com Page 2 of 2

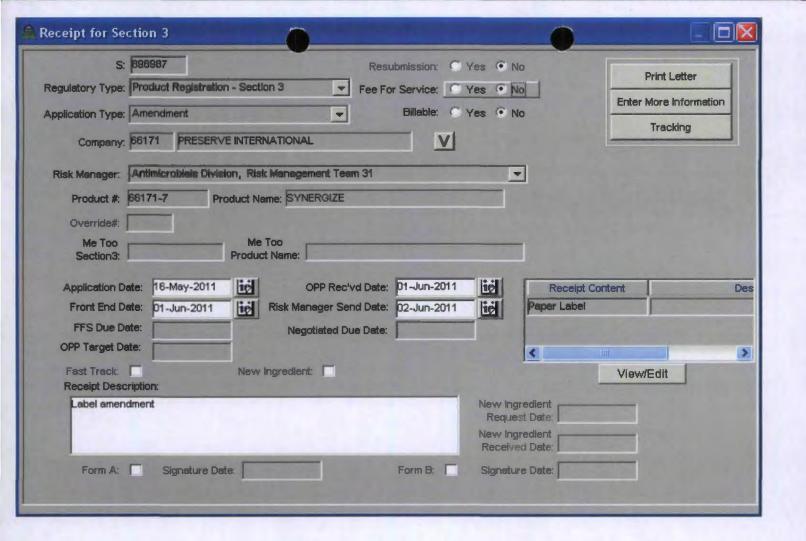
#### **DOT SHIPPING NAME**

UN3264, Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, PG III

5/24/11

## RISK ASSIGNMENT FORM Antimicrobial Division/Regulatory Management Branch I

A		С	ompleted b	y Product	Manag	ger				
PRODUCT	REVIEWER:	TI	a con			RMBI	TEAM 3	1		
Type of Act	ion:	Tr. Lakel	revie				e Symbol/Reg			
Decision N	10.450321				Fee	for Service A	ction Code:			
FQPA Actio	n Code: 30	Non-FQPA	Non-FQPA Action Code:				PRIA FEE AMOUNT:			
	30	MONTH 4	DAY			YEAR				
APPLICATION	ON DATE	5	25				2011			
EPA PIN DA	TE	6	1				2011			
DATE PM RE	CEIVED FROM						2011			
DATE SENT	TO SCIENCE									
DATE RECE SCIENCE	EIVED FROM									
DATE DUE	то РМ	th 9	1 30	29		2011				
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASS Environm Fate	ental	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/ Residue		
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			See	flagged le	Hursi	njudi chedica	ill earlier 1-	ekrs!		
ATTACHME	NTS: -LABEL	ING -	CSF(S)	-DAT	Α	-ОТН	IERS			
В			or Arctic S	lope Conti	act O	nly				
Contra	act No.: 0052	ARCTI	C SLOPEIN	IANAGER						
Final 7	ask: Signature					(Total hrs	3)			
C Review	wer Comments:							***		
DATE FEE I	PAID:		RESPON	ISE CODE:		RESP	ONSE DATE:			





### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 2, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

GARY GAUMER PRESERVE INTERNATIONAL PO Box 17003 RENO, NV 89511-

PRODUCT NAME: SYNERGIZE

COMPANY NAME: PRESERVE INTERNATIONAL

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 66171-7 EPA RECEIPT DATE: 06/01/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

## Fee for Service

{896987v~

This package includes the following	for Division
<ul> <li>New Registration</li> <li>Amendment</li> <li>Studies? □ Fee Waiver?</li> <li>volpay % Reduction:</li> </ul>	<ul><li>AD</li><li>BPPD</li><li>RD</li><li>Risk Mgr. 31</li></ul>
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	896987 66171-7 6/1/2011
This item is NOT subject t	o FFS action.
Action Code:	Parent/Child Decisions:
Requested:	
Granted:	
Amount Due: \$	
Inert Cleared for Intended Use	Uncleared Inert in Product
Reviewer: Icam a	Date: 06-02-2011
Remarks: FQPA 300 label re	



### Re: Your amendment for 66171-7 Gary E. Gaumer to: Tracy Lantz

08/17/2011 03:42 PM

1 attachment



Hello,

Attached is the formulator's exemption.

As to the dilutions for the continuous feed method, let's put a range of 1 - 4 ounces per 100 gallons of water.

Thanks,

GG

On Aug 15, 2011, at 3:49 PM, Lantz.Tracy@epamail.epa.gov wrote:

> We received your amendment at the beginning of June. It is coded as a > 307 (120 day review time frame) due to the need to review data > compensation. > I am still in the process of reviewing your application, but would like > to you to make a few corrections at this time. I may have additional > comments as I continue to review your information. > Please provide a revised formulator's exemption statement. Your current > form does not agree with your CSF as it does not list all alternate > sources of glutaraldehyde. Please provide a revised form with an > original signature. You may scan the form and send it to me via e-mail. > Your directions for air washers are not in agreement with FAD 1 which > was provided to your previously. Revise the Continuous Feed method, > subsequent dose to read as follows: "Maintain this treatment level by > starting a continuous feed of gallons of ounces per > water lost to blowdown. Badly fouled systems... " Just provide me with > information on the rate to be used in this section. I'll incorporate > your correction in to one of the comments in my letter. > (Embedded image moved to file: pic31111.jpg) <pic31111.jpg>



Fw: Your amendment for 66171-7
Tracy Lantz to: Gary E. Gaumer

08/16/2011 09:57 AM

In addition, please provide a certification with respect to citation of data form. Indicate that you are using the selective option. Based on your current matrix you do not need to offer compensation to any other company. Please sign the form and send as a pdf. Thanks

**Tracy Lantz** 

Regulatory Team 31
Antimicrobials Division

Dracy Lax

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

---- Forwarded by Tracy Lantz/DC/USEPA/US on 08/16/2011 09:55 AM -----

From: Tracy Lantz/DC/USEPA/US

To: "Gary E. Gaumer" < GEGAUMER@PRESERVEINC.COM>

Cc: Velma Noble/DC/USEPA/US@EPA

Date: 08/15/2011 06:49 PM Subject: Your amendment for 66171-7

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Your directions for air washers are not in agreement with FAD 1 which was provided to your previously. Revise the Continuous Feed method, subsequent dose to read as follows: "Maintain this treatment level by starting a continuous feed of \_\_\_\_\_\_ ounces per \_\_\_\_\_ gallons of water lost to blowdown. Badly fouled systems..." Just provide me with information on the rate to be used in this section. I'll incorporate your correction in to one of the comments in my letter.

**Tracy Lantz** 

Regulatory Team 31
Antimicrobials Division

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481



### Your amendment for 66171-7 Tracy Lantz to: Gary E. Gaumer

Cc: Velma Noble

08/15/2011 06:49 PM

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**Tracy Lantz** 

Regulatory Team 31
Antimicrobials Division

Dracy Lak

U. S. Environmental Protection Agency

Phone: (703) 308-6415 FAX: (703) 308-8481

# Study Information For Product Registration - Section 3 66171-7

MRID	Citation	Receipt Date			
44433700	Preserve International. (1997) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Synergize Disinfectant. Transmittal of 6 Studies.	24-Nov- 1997			
44433701	Gaumer, G. (1997) Product Chemistry: Synergize: Lab Project Number: PI-SYN-01-97: Unpublished study prepared by Preserve International. 69 p.	24-Nov- 1997			
44433702	Juntunen, K. (1997) Synergize: Selected Physical and Chemical Characteristics: Lab Project Number: 97-005. Unpublished study prepared by DiverseyLever. 22 p.				
44433703	Mason, M. (1997) Synergize: Preliminary Analysis and Precision of Analytical Method Used to Validate Certified Limits: Final Report. Unpublished study prepared by Mason Chemical Co. 5 p.	24-Nov- 1997			
44433704	Bell, J. (1997) Synergize: Preliminary Analysis and Precision of Analytical Method Used to Validate Certified Limits: Final Report. Unpublished study prepared by Barrow-Agee Labs, Inc. 7 p.	24-Nov- 1997			
44433705	Gammon, R. (1997) AOAC Disinfectant Testing of Synergize in the Presence of 5% Blood Serum and 1000 PPM Calcium Carbonate Hard Water: Lab Project Number: 97-04. Unpublished study prepared by Presque Isle Cultures. 32 p.	24-Nov- 1997			
44433706	Gammon, R. (1997) AOAC Disinfectant Testing of Synergize in the Presence of 5% Blood Serum and 1000 PPM Calcium Carbonate Hard Water: Addendum: Lab Project Number: 97-04. Unpublished study prepared by Presque Isle Cultures. 29 p.	24-Nov- 1997			
44569500	Preserve International (1998) Submission of Toxicity Data in Support of the Application for Registration of Synergize. Transmittal of 6 Studies.	29-May- 1998			
44569501	Cerven, D. (1997) Single Dose Oral Toxicity in Rats/LD 50 in Rats: (Synergize): Lab Project Number: MB 97-5770.01: 67-04. Unpublished study prepared by MB Research Labs., Inc. 15 p.	29-May- 1998			
44569502	Cerven, D. (1997) Acute Dermal Toxicity in Rabbits/LD 50 in Rabbits: (Synergize): Lab Project Number: MB 97-5770.02: 175-04. Unpublished study prepared by MB Research Labs., Inc. 14 p.	29-May- 1998			
44569503	Kieffer, L. (1997) Primary Dermal Irritation in Rabbits: (Synergize): Lab Project Number: MB 97-5770.03: 166-05. Unpublished study prepared by MB Research Labs., Inc. 11 p.	29-May- 1998			
44569504	Cerven, D. (1997) Primary Eye Irritation/Corrosion in Rabbits: (Synergize): Lab Project Number: MB 97-5770.04: 236-04. Unpublished study prepared by	29-May- 1998			



	MB Research Labs., Inc. 13 p.	
44569505	Cerven, D. (1997) Acute Inhalation Toxicity in Rats/LC 50 in Rats: (Synergize): Lab Project Number: MB 97-5770.05: 318-10. Unpublished study prepared by MB Research Labs., Inc. 38 p.	29-May- 1998
44569506	Hoff, T. (1997) Delayed Contact Dermal Sensitization TestBuehler Method: (Synergize): Lab Project Number: MB 97-5770.06: 112B-03. Unpublished study prepared by MB Research Labs., Inc. 17 p.	29-May 1998
45147100	Preserve International (2000) Submission of Efficacy Data in Support of the Application for Registration of Synergize. Transmittal of 1 Study.	16-Jun- 2000
45147101	Gammon, R. (1997) A.O.A.C. Fungicidal Product Test: Preserve International, Synergize: Lab Project Number: 97-3. Unpublished study prepared by Presque Isle Cultures Report. 23 p.	16-Jun- 2000
46391300	Preserve International (2004) Submission of Efficacy Data in Support of the Registration of Synergize. Transmittal of 1 Study.	18-Oct- 2004
46391301	Miller, M. (2004) Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces: Porcine Respiratory & Reproductive Syndrome Virus: Synergize: Final Study Report. Project Number: PRE08061404/PRRS, A02359. Unpublished study prepared by ATS Labs. 14 p.	18-Oct- 2004
46770300	Preserve International (2006) Submission of Product Chemistry Data in Support of the Amended Registration of Synergize. Transmittal of 2 Studies.	27-Feb- 2006
46770301	Miller, M. (2006) Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces: Synergize: Avian Influenza A (H3N2) Virus (Avian Reassortant): Final Study. Project Number: A03539, PRE08110705/AFLU/2. Unpublished study prepared by ATS Labs. 15 p.	27-Feb- 2006
46770302	Jeske, A. (2006) AOAC Use-Dilution Method: Escherichia coli (F-18) - Clinical Isolate (F-18): Synergize: Final Study. Project Number: A03572, PRE08122205/UD. Unpublished study prepared by ATS Labs. 15 p.	27-Feb- 2006
46908800	Preserve International (2006) Submission of Efficacy Data in Support of the Amended Registration of Synergize. Transmittal of 1 Study.	28-Jul- 2006
46908801	Blaszak, L. (2006) Virucidal Effectiveness Test; Post Weaning Multisystemic Wasting Syndrome (Porcine circovirus Type 2): Final Report. Project Number: 366/107, 366/1/05/09/06. Unpublished study prepared by MicroBioTest, Inc. 22 p.	28-Jul- 2006

Copy 1 – EPA Copy 2 - Applicant copy

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h 8570-27 (Rev. 06-2004)



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

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comments regarding burden estimate or any other aspect of this collection of information, including Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Aveto this address.	uding suggestions for reducing the burden to: Director, Collection nue, N.W., Washington, DC 20460. Do not send the completed form
Certification with Respect to 0	Citation of Data
Applicant's/Registrant's Name, Address, and Telephone Number Preserve International, PO Box 17003, Reno, NV 89511	EPA Registration Number/File Symbol 66171-7
Active Ingredient(s) and/or representative test compound(s) Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride	Date August 17, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 Farm, Indoor non-food, animal, cooling and processed water	Product Name Synergize
NOTE: If your product is a 100% repackaging of another purchased EPA-registers submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)	ed product labeled for all the same uses on your label, you do not need to n 8570-27).
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies sent offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPI	PORT (Check one method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
SECTION II: GENERAL	OFFER TO PAY
[Required if using the cite-all method or when using the cite-all option under the select like the cite-all options are cited to the cite-all option under the select like the cite all options are cited to the cite all options are cited to the cited the cited the cite all options are cited to the cited the cite all cited the cited the cited the cited the cited the cited th	
SECTION III: CERT	TIFICATION
I certify that this application for registration, this form for reregistration, or the pata-Call-in response. In indicated in Section I, this application is supported by all data in the Agency's files the substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sources.	n addition, if the cite-all option or cite-all option under the selective method is at (1) concern the properties or effects of this product or an identical or is a type of data that would be required to be submitted under the data ght the initial registration of a product of identical or similar composition and
certify that for each exclusive use study cited in support of this registration	or reregistration, that I am the original data submitter or that I have obtained

the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either. (a) I am the original data submitter, (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date 8/17/11	Typed or Printed Name and Title Gary E. Gaumer, President
EDA Form 8570/24/42 2000) Electronic and Delectronic and Delec	la Cubmit anti Danas comina	



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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Information Management Division (2137), U.S. Environmental Protection Agency, 40 Do not send the completed form to this address.	1 M Street, S.W., W	/ashington, DC 20460.		
Certification with Respect	to Citation of	Data		
Applicant's/Registrant's Name, Address, and Telephone Number Preserve International, PO Box 17003, Reno, NV 89511		EPA Registration Number/File Symbol 66171-7		
Active Ingredient(s) and/or representative test compound(s) Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride,	Glutaraldehyde	Date May 25, 2011		
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 Farm, Indoor non-food, animal, cooling and processed water treatment	)	Product Name Synergize		
NOTE: If your product is a 100% repackaging of another purchased EPA-registers submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement)		or all the same uses on your label, you do not need to		
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	ent offers of compensation (the Data Metrix form should		
SECTION I: METHOD OF DATA SUPP	PORT (Check one n	nethod only)		
l am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	ng the selective method of support (or cite-all option e selective method), and have included with this form a ed list of data requirements (the Data Matrix form must be		
SECTION II: GENERAL	OFFER TO PAY	• •		
I hereby offer and agree to pay compensation, to other persons, with regard to		s application, to the extent required by thi to.		
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sould uses.  I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.  I certify that for each study cited in support of this registration or reregistration the written permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(amount and terms of compensation, if any, to be paid for the use of the study.  I certify that in all instances where an offer of compensation is required, con accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.  I certify that the statements I have made on this form and all attachments who in the public by fine or imprison.	a addition, if the cite it (1) concern the prise a type of data the ght the initial registration, the or reregistration, the content is not an existed in support of I have notified in we c)(2)(B) of FIFRA; a bies of all offers to probe submitted to the into deny, cancel or ments to It are true	-all option or cite-all option under the selective method is operties or effects of this product or an identical or at would be required to be submitted under the data ation of a product of identical or similar composition and that I am the original data submitter or that I have obtained at I am the original data submitter or that I have obtained clusive use study, either: (a) I am the original data this application; (c) all periods of eligibility for riting the company that submitted the study and have and (ii) to commence negotiations to determine the analysis of their delivery in Agency upon request. Should I fail to produce such a suspend the registration of my product in conformity with accurate, and complete. I acknowledge that any		
Signature	Date	Typed or Printed Name and Title		
187 ru	5/17/11	Gary E. Gaumer, President		

Form Approved OMB No. 2070-0060



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	DAT	A MATRIX	•		
Date May 24, 2011			EPA Reg No./File Symbol 66171-7	: ::	Page of 3
Applicant's/Registrant's Name & Address  Preserve International, PO Box 17003, Reno, NV 89511		Product Synergize			
Ingredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Submission of Product Chemistry and Efficacy Data	44433700	Preserve International	Own	
	in support of the application for registration of Synergize				
L.	Disinfectant.				
61-1	Product Identity & Disclosure of Ingredients	44433701	Preserve International 1997	Own	
61-2	Product Identity - Beginning Materials & Mfg. Process	44433701	Preserve International	Own	+
61-3	Product Identity - Discussion of Formation of Impurities	44433701 /	Preserve International	Own	
52-2	Analysis of Ingredients - Certification of Limits	44433701 /	Preserve International	Own	
3-0	Reports of Multiple Physical/Chemical Characteristics	44433701 /	Preserve International	Own	
3-0	Selected Physical Characteristics	44433702 /	Preserve International	Own	
2-1	Analysis of Ingredients-Preliminary Analysis of Product	44433703 /	Preserve International	Own	
2-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433703	Preserve International	Own	
2-1	Analysis of Ingredients-Preliminary Analysis of Product	44433704	Preserve International	Own	
2-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433704 /	Preserve International	Own	
	AOAC Disinfectant Testing (Efficacy)	44433705 /	Preserve International	Own	
1	/ AOAC Disinfectant Testing (Efficacy)-Addendum 1		Preserve International	Own	
Signature			Name and Title		Date
1271			Gary E. Gaumer, President		May 24, 2011

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	DAT	A MATRIX			
Date May 24, 2011  Applicant's/Registrant's Name & Address 3		EPA Reg No./File Symbol 66171-7		Page2 of 3	
		Product Synergize			
Ingredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Toxicity Data Submission Cover Sheet	44569500	Preserve International	Own	
31-1	Acute Tox & Irritation - Acute Oral Toxicity	44569501 / .	Preserve International \qq\	Own	
31-2	Acute Tox & Irritation - Acute Dermal Toxicity	44569502	Preserve International	Own	
1-5	Acute Tox & Irritation - Primary Dermal Irritation	44569503	Preserve International	Own	
1-4	Acute Tox & Irritation - Primary Eye Irritation	44569504	Preserve International	Own	
11-3	Acute Tox & Irritation - Acute Inhalation Toxicity	44569505	Preserve International	Own	
11-6	Acute Tox & Irritation - Dermal Sensitization	44569506	Preserve International	Own	
	Fungicidal Data Submission Cover Sheet	45147100	Preserve International	Own	
	AOAC Fungicidal Product Test - Efficacy Data	45147101	Preserve International	Own	
	Porcine Respiratory & Reproductive Cover Sheet	46391300	Preserve International	Own	
	Porcine Respiratory & Reproductive Syndrome Virus Data	46391301	Preserve International \$604	Own	
	Avian Influenza A (H3N2) Virus Cover Sheet	46770300 4	Preserve International	Own	
	Avian Influenza A (H3N2) Virus Data	46770301 /	Preserve International 2006	Own	
	Escherichia coli (F18) Cover Sheet	46770300	Preserve International	Own	
-	Escherichia coli (F18) Data	46770302 /	Preserve International 2666	Own	
Signature Signature			Name and Title  Gary E. Gaumer, President		Date





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		DATA MATRIX	•		
Date May 24, 2011			EPA Reg No./File Symbol 66171-7		Page3 of 3
Applicant's/Registrant's Name & Address Preserve International, PO Box 17003, Reno, NV 89511			Product Synergize		
Ingredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Porcine circovirus Type 2 Cover Letter	46908800	Preserve International	Own	
	Porcine circovirus Type 2 Data	46908801	Preserve International 2006	Own	
2.4					
Signature &			Name and Title		Date / //
OT.	2		Gary E. Gaumer, President		5/24/1

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WASHINGTON, D.C. 20460

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send the form to this address.					
		DATA MATRIX			
Date May 24, 2011			EPA Reg No./File Symbol 66171-7		Page 1 of 3
Applicant's/Registrant's Name & Ac	ddress		Product		
Preserve International, PO Box 170	003, Reno, NV 89511		Synergize		
ngredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preserve International	Own	
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Signature 4			Name and Title		Date
202			Gary E. Gaumer, President		May 24, 2011



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		DATA MATRIX			
Date May 24, 2011			EPA Reg No./File Symbol 66171-7		Page2 of
Applicant's/Registrant's Name & Address			Product Synergize		
ngredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preserve International	Own	
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gnature #			Name and Title Gary E. Gaumer, President		Date ///



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Date May 24, 2011			EPA Reg No./File Symbol 66171-7		Pages of 3
Applicant's/Registrant's Name & A	ddress		Product		
Preserve International, PO Box 170	003, Reno, NV 89511		Synergize		
Ingredient Alkyl dimethyl benzyl a	mmonium chloride, Glutaraldehyde				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preserve International	Own	
			Preserve International	Own	
Signature			Name and Title		Date
			Gary E. Gaumer, President		



World Headquarters P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607
 Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446
 California Operation 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

May 25, 2011

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

- Addition of directions for use: AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS.
- Addition of Canine parvovirus and associated directions for use in:
  VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/
  ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/
  ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/
  PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING
  FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK
  SHOPS DISINFECTION DIRECTIONS. Since Canine parvovirus is not a
  crossover virus, we have not submitted thie data; however, we do have the data
  ion our file if the EPA should ever desire us to submit it for their review.

We have included the required: 1) USEPA Form 8570-1, Application for Pesticide, 2) Formulator's Exemption for both active ingredients, 3) Certification with respect to citation of data, 4) Data matrix and 5) six copies of the proposed labeling.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaume

President

Please read instructions on	reverse before complete	ing form.	-		Form Appr	roved	OMB No.	2070-006	O. Approval expires 2-28-9
<b>\$EPA</b>	United States Environmental Protection Agency Washington, DC 20460					V	Registra Amenda Other		OPP Identifier Number
		Application	n for f	Pesticio	le - Secti	ion			
1. Company/Product Numbe 66171-7				2. EPA I Noble	Product Mana	ger			oposed Classification  None Restricted
4. Company/Product (Name) SYNERGIZE				PM# 31					Nestricted
Preserve - Pobuy 178 Reno NV Check if this	plicant (Include ZIP Cod Enternation 003 89511 is a new address	10)0		(b)(i), m to: EPA R					FIFRA Section 3(c)(3) mposition and labeling
			Sec	tion - I				arriva.	
Amendment - Explain  Resubmission in resp  Notification - Explain  Explanation: Use addition Addition of directions for use LABORATORY/ANIMAL RES FACILITIES/BREEDING AND	below.  below.  nal page(s) if necessary for: VETERINARY PRACEARCH CENTERS/ANI	/. (For section	CS)/ANIMA	L CARE F	/PET SHOP/K	pplica ain be	ed ation. slow. LABORATO ELS/ANIMAT	RYANIMA HUSBANI	DRY/ANIMAL BREEDING
RECIRCULATING COOLING					7107111		•		•••••
			Sect	ion - II	1				
1. Material This Product Wil	Be Packaged In:			-					
Child-Resistant Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water		No. per container		2. Type of	Container  Metal Plastic Glass Paper Other (S	
3. Location of Net Contents	Information	4. Size(s) Ret 275g,25	tail Contain				cation of Lal		ons
6. Manner in Which Label is		Lithog Paper Stenci	raph glued lad		<b>✓</b> Other	Sie	eve		
			Sect	ion - I\	1				
1. Contact Point (Complete	items directly below for	or identificatio	n of indivi	idual to be	contacted, h	f nec	essary, to pi	ocess this	application.)
Name Gary E. Gaumer			Title Presiden	t				Telephone 500 079-5	e No. (Include Area Code)
	ments I have made on my knowlingly false or m		all attach					mplete.	6. Date Application Received (Stamped)
2. Signature			3. Title President						
4. Typed Name Gary E. Gaumer				May	16, 2011				

# Material Sent for Data Extraction

Reg # 66171-7

Description:	
☐ Material(s) Sent to Data E	extraction Contractors:
☐ New Stamped Label	Dated
Notification Dated _	
☐ New CSF(s) Dated _	<u></u>
Other:	
☐ Decision #:	
☐ Other Action/Comments:	
*	
Attach this coversheet to the top of must be well organized and clipped. Then give the material with this confirmation Services Center (Room	together, NOT STAPLED. versheet to staff in the
Reviewer: Mixon + M	eam 31
Phone: 203 308 8032 Divis	ion: AD
Date: 6 /24///	

NOTIFICATION Date Reviewed: \_ Reviewed By: Tam

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



## EPA United States Office of Pesticide Programs

Gary E. Gaumer, Preserve International. P.O. Box 17003, Reno, NV 89511

JUL 1 - 2011

Subject:

Synergize

EPA Registration No.: 66171-7 Notification Date: May 27, 2011 EPA Receipt Date: June 01, 2011

Submission #: 897610

Dear Mr. Gaumer,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

## Proposed notification request for alternative brand name:

Alternative brand name: "Champion".

### **General Comments**

Based on a review of the submitted materials your notification of a request for an alternative brand name for your product, "Synergy", is acceptable.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Product Manager -31

Regulatory Management Branch Antimicrobials Division (7510P)

			CONCURRENC	æs		
SYMBOL	•					
SURNAME )		,				
DATE			***************************************			

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

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<b>ŞEPA</b>		Environn	nental	Pre	0

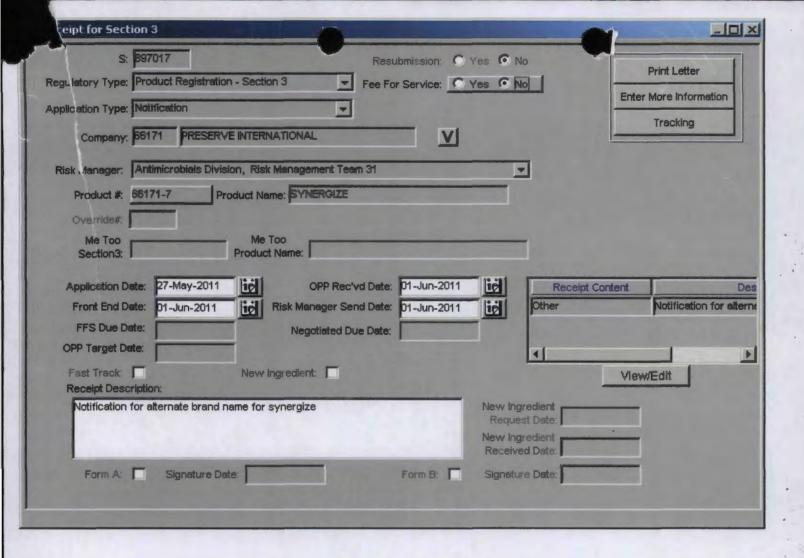
## **Environmental Protection Agency**

Form Approved.	OMB 1 0-0060
	Registration Amendment
×	Other

**OPP Identifier Number** 

**Print Form** 

	Wast	hington, DC 20	0460		× Other			
		Applicati	ion for Pes	ticide - Sec	tion I			
1. Company/Product Number 66171-7	r			2. EPA Product Manager 31			oposed Classification	
4. Company/Product (Name) Synergize	)		PM	oble			None Restricted	
5. Name and Address of Applicant (Include ZIP Code)  Preserve International  PO Box 17003  Reno, NV 89511  Check if this is a new address			(b) to: Ef	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name				
			Section	1 - 11				
Amendment - Explain Resubmission in resp  X Notification - Explain	ponse to Agency lette	er dated		Agency let	od labels in respo ster dated Application, plain below,	nse to		
Preserve International he Companion.	redy submits this i	iotineador (	Section		yiergize. The u	and the state of t		
1. Material This Product Wi	l Be Packaged In:							
Child-Resistant Packaging Yes*  X No  * Cartification must	Unit Packaging Yes X No If "Yes" Unit Packaging wg	No. par	Yes No	No. per		Metal Plastic Glass Paper Other (5	••••	
be submitted		1		1///	I S I service of			
3. Location of Net Contents  X Label (	Container	8 02	letail Container .; 16 • 2, .55, 30, 15	4x1,3202 52x2.5	5. Location of IX On La	hal	npenying product	
6. Manner in Which Label is	Affixed to Product	Litho	ograph or glued ociled	X Oth	Sleeve		*****	
			Section	- IV			• • • • • • •	
1. Contact Point /Complete	items directly below	for identificat	tion of individua	to be contacted	, if necessary, to	process this	application.)	
Name Gary E. Gaumer			Title President			Telephon	e 140. (include Area Code)	
I cartify that the state I acknowledge that a both under application	knowingly false or		nd all attachmen				6. Date Application Received (Stamped)	
2. Signature			3. Title President					
17015	-							
4. Typed Name Gary E. Gaumer			5. Date May 27, 2011					



# Material Sent for Data Extraction

Reg # 66/7/-2

Des	cription	
D	Materia	I(s) Sent to Data Extraction Contractors:
		New Stamped Label Dated
		Notification Dated
	卤	New CSF(s) Dated
		Other:
	Decision	#:
	Other Ac	ction/Comments:
must Then Infor	be well of give the mation S	versheet to the top of the material or jacket. It organized and clipped together, NOT STAPLED. material with this coversheet to staff in the ervices Center (Room S-4900).  E. Or'Guenbloh
		7-8199 Division: AD
		.69.11.

Gary E.Gaumer Preserve International P.O. Box 3135 Turlock, CA 95381 MAY 10 2011

SUBJECT:

Synergize

EPA Registration Number: 66171-7 Application Dated: December 28, 2010

Receipt Dated: January 4, 2011

Dear Ms. Holcombe:

The following amendment, submitted under the provisions of section 3 (c) 9 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable.

Submission of Alternate Formulations.

The proposed Confidential Statements of Formulas (CSFs) dated 11/22/2010, for alternate formulations are acceptable. For details see attached associated chemistry review.

## **General Comments**

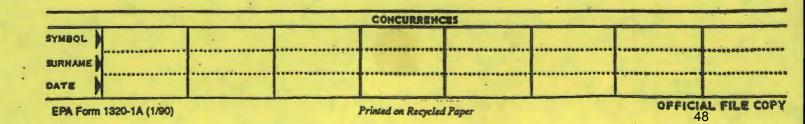
This letter supersedes the letter dated March, 31, 2011. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Singerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

May 03, 2011.

DP BARCODE: D385357 (REVISED)

MRID: N/A

SUBJECT: Synergize

REG. NO. OR FILE SYMBOL 66171-7

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS (PC Codes) Alkyl dimethyl benzyl ammonium chloride (069175)

Glutaraldehyde (043901)

° H

CAS Number: 68391-01-5, 111-30-8.

TEST LAB: N/A

SUBMITTER: Preserve International

GUIDELINE: N/A

COMMODITIES: Formulation

REVIEWER: Salvador Rodríguez

ORGANIZATION: AD

APPROVER: Karen P. Hicks

REVISED DATE: 05/03/11.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

May 03, 2011.

## **MEMORANDUM**

Product Chemistry Review for EPA Reg # 66171-7 Subject: From: Salvador Rodríguez, Chemist Product Science Branch, CT Team Antimicrobials Division (7510P) Karen P. Hicks, CT Team Leader Thru: Product Science Branch Antimicrobials Division (7510P) To: Velma Noble/Tracy Lantz PM Team 31 Antimicrobials Division (7510P) APPLICANT: Preserve International. 362 Action code: Due date: 04/04/11. **Product Formulation** Active Ingredient(s) % by wt. Alkyl dimethyl benzyl ammonium chloride ............26.00 Glutaraldehyde......7.00

66171-7\_D385357\_REV\_PreserveInternational Page 2 of 3

## **BACKGROUND:**

The registrant, Preserve International, has submitted the CSFs for the alternate formulation (synergize-orange) and (synergize-orange-NF), for the disinfectant, fungicide and virucide non-integrated end-use product, **Synergize**. The registrant is adding a new fragrance to the formulation. Product Chemistry Reviewer has received the following documents:

- A letter dated, 12/28/10.
- Confidential Statements of Formula (CSFs) dated 11/22/10, for alternate (synergize orange) and (synergize-orange-NF) formulations.
- Confidential Statement of Formula (CSF), dated 09/11/03, for the basic formulation.

## **FINDINGS:**

- 1. The CSFs, dated 11/22/10, for alternate formulations are revised.
- 2. The CSF and the label have the same nominal.
- 3. All certified limits meet the EPA standard certified limits.
- 4. The registrant used the CAS number is See recommendations.
- 5. The registrant used the CAS number 11-30-8 for one of the active ingredients (AI). The correct CAS number is 111-30-8
- 6. The registrant used the CAS number 68391-05-5 for one of the active ingredients (AI). The correct CAS number is 68391-01-5

### CONCLUSIONS:

The CSFs, dated 11/22/10, for the alternate (synergize-orange) and (synergize-orange-NF), formulations are acceptable. The proposed technical amendment meets the EPA Guidelines.

## **RECOMMENDATIONS:**

The registrant must correct the CAS numbers for both of the active ingredients (AIs), and for the solvent. See findings 4, 5 & 6.

Gary E. Gaumer Preserve International P.O. Box 3135 Turlock, CA 95381

Subject:

Synergize

EPA Registration No.: 66171-7

Amendment Dated: December 28, 2010 EPA Receipt Date: January 4, 2011

Dear Mr. Gaumer,

This letter acknowledges receipt of the amendment identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRRA), as amended.

Submission of Alternate Formulations

Based on a review of the submitted information this amendment is unacceptable due to the concerns listed below. You have submitted two alternate Confidential Statements of Formulations (CSFs) dated 11/22/10. A number deficiencies have been identified.

- 1) Correct the CAS number of the active ingredient to read: 68391-01-5.
- 2) Correct the CAS number of the active ingredient Glutaraldehyde to read: 111-30-8.
- 3) The perfume: has only been used as an active ingredient. Submit information for clearance as a new non-food inert ingredient. The following website provides guidance on this process: http://www.epa.gov/opprd001/inerts/

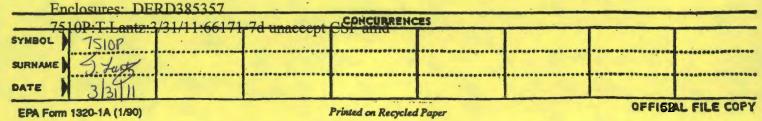
Please find the chemistry review attached. Submit the requested inert information and revised CSFs addressing the issues noted above. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Velma Noble.
Product Manager (31).
Regulatory management Branch I.

Sincerely.

Antimicrobials Division (7510P)

3 1 2011





## **DATA PACKAGE BEAN SHEET**

Date: 06-Jan-2011
Page 1 of 1

Decision #: 443869

DP #: (385357)

**NON PRIA** 

Parent DP #:

**Submission #: 888459** 

## \* \* \* Registration Information \* \* \*

Registration:	66171-7 - SYNERGIZE
Company:	66171 - PRESERVE INTERNATIONAL
Risk Manager:	RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855
Risk Manager Reviewer:	Tracy Lantz TLANTZ
Sent Date:	06-Jan-2011 Calculated Due Date: 04-Apr-2011 Edited Due Date:
Type of Registration:	Product Registration - Section 3
Action Desc:	(362) FORMULA CHANGE; TECHNICAL;
Ingredients:	043901, Glutaraldehyde(7%) 069175, Alk i* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18)(26%)
	* * * Data Package Information * * *
Expedite:	○ Yes ● No Date Sent: 06-Jan-2011 Due Back:
DP Ingredient:	043901, Glutaraldehyde
	069175, Alkyl* dimethyl benzyl ammonium chloride *(67%C12, 25%C14, 7%C16, 1%C18)
DP Title:	·
CSF Included:	Yes No Label Included: Yes No Parent DP#:  Date In Date Out
Organization: AD / P	SB Last Possible Science Due Date: 18-Feb-2011
Team Name: CTT	16/4 02/03/11 Science Due Date: 2/18/61
Reviewer Name:	al Vactor 1/6/11 02/03/11 Sub Data Package Due Date: 3/7/11
Contractor Name:	
	* * * Studies Sent for Review * * *
	No Studies
	* * * Additional Data Package for this Decision * * *
	No Additional Data Packages
	* * * Data Package Instructions * * *
Registrant has submitte	ed CSF to be reviewed.
Please 10	all label + pelet



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

February 03, 2011.

DP BARCODE: D385357

MRID: N/A

SUBJECT: Synergize

REG. NO. OR FILE SYMBOL 66171-7

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [] OR End-use Product [X]

INGREDIENTS (PC Codes) Alkyl dimethyl benzyl ammonium chloride (069175)

Glutaraldehyde (043901)

° H

CAS Number: 68391-01-5, 111-30-8.

TEST LAB: N/A

SUBMITTER: Preserve International

GUIDELINE: N/A

COMMODITIES: Formulation

REVIEWER: Salvador Rodríguez

ORGANIZATION: AD

APPROVER: Karen P. Hicks

APPROVED DATE: 02/03/11.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 03, 2011.

## **MEMORANDUM**

Subject: Product Chemistry Review for EPA Reg # 66171-7

From: Salvador Rodríguez, Chemist

Product Science Branch, CT Team

Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader

Product Science Branch

Antimicrobials Division (7510P)

To: Velma Noble/ Tracy Lantz

PM Team 31

Antimicrobials Division (7510P)

APPLICANT: Preserve International.

Action code: 362

**Due date:** 04/04/11.

Product Formulation Active Ingredient(s)

% by wt.

Alkyl dimethyl benzyl ammonium chloride .......26.00

Glutaraldehyde......7.00

**BACKGROUND:** 

66171-7\_D385357\_PreserveInternational

### BACKGROUND:

The registrant, Preserve International, has submitted the CSFs for the alternate formulation (synergize-orange) and (synergize-orange-NF), for the disinfectant, fungicide and virucide non-integrated end-use product, **Synergize**. The registrant is adding a new fragrance to the formulation. Product Chemistry Reviewer has received the following documents:

- A letter dated, 12/28/10.
- Confidential Statements of Formula (CSFs) dated on 11/22/10, for alternate (synergize orange) and (synergize-orange-NF) formulations.
- Confidential Statement of Formula (CSF), dated 09/11/03, for the basic formulation.

### **FINDINGS:**

- 1. The CSFs, dated 11/22/10, for alternate formulations are revised.
- 2. The CSF and the label have the same nominal.
- 3. All certified limits meet the EPA standard certified limits.
- 4. This perfume ( has been only used as an active ingredient (AI). Please see Recommendation section
- 5. The registrant used the CAS number 11-30-8 for one of the active ingredients (AI). The correct CAS number is 111-30-8
- 6. The registrant used the CAS number 68391-05-5 for one of the active ingredients (AI). The correct CAS number is 68391-01-5

## **CONCLUSIONS:**

The CSFs, dated 11/22/10, for the alternate (synergize-orange) and (synergize-orange-NF), formulations are not acceptable. The proposed technical amendment is not acceptable.

### **RECOMMENDATIONS:**

- 1) The registrant must correct the CAS numbers for both of the active ingredients (AIs). See findings 5 & 6.
- 2) This perfume has been only used as an active ingredient (AI). The information on preparing a new non-food inert ingredient request can be accessed here: http://www.epa.gov/opprd/001/inerts/

66171-7 D385357 PreserveInternational



World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

December 28, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International has received your December 20, 2010 letter in which you request several revisions to our recently submitted alternate formula requests for identifiers: Synergize-orange, and Synergize-orangenf)

Please find the revisions attached to this cover letter.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary F. Gaumer President

TOTAL B. GENTLE

Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511 DEC 3 0 2010

Subject:

Synergize

EPA Registration No.: 66171-7

Amendment Date: September 1, 2010 EPA Receipt Date: September 10, 2010

Dear Mr. Gaumer,

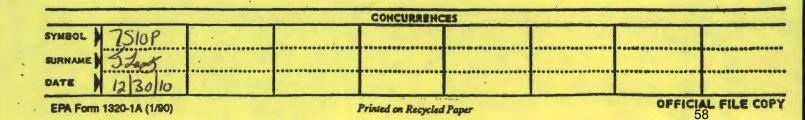
The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3 (C) (7) (A) as amended, is unacceptable due to the concerns listed below:

 Adding directions for air washers, industrial scrubbing systems, recirculating cooling and process water systems

## **Deficiencies**

The addition of the sites identified above are new uses (industrial water treatment) for this product. These uses differ significantly from the currently approved uses on this label. Although these uses are not new for either of the active ingredients in your product and seem to fall within the range of previously accepted dosage rates for this use, these uses are new for this product and thus data compensation is required.

Although you were originally contacted regarding this concern on 12/9/10, we have not received the necessary data compensation forms at this time. These forms must be submitted in order for the Agency to approve these uses. Please refer to our previous e-mail messages. Should you need additional information on data compensation, please see the Agency Blue Book at: http://www.epa.gov/pesticides/bluebook/



## Other Concerns

In addition, revise the label to include the following changes:

- 1) Revise the "Poultry House and Livestock Buildings" directions along with the associated "Note" to be in agreement with PR Notice 2000-5 which indicates the need for mandatory statements in the directions for use. The use of the word "should" is not acceptable.
- 2) Revise the "Air washers, Industrial Scrubbing Systems, Recirculating Cooling and Process Water Systems" directions to be in agreement with PR Notice 2000-5 which indicates the need for mandatory statements in the directions for use. The use of the words "may" and "may be" are not acceptable. In addition, refer to the enclosed FAD-1 for guidance as to the type of information that is required in this section and revise your label accordingly.
- 3) Revise your label to make clear that fogging for Hatchery Rooms, Incubators and Hatchers, Poultry Houses and Livestock Buildings is only to be used as an <u>adjunct treatment</u> by deleting the statement: "Fogging is to be used as an adjunct to acceptable manual cleaning and disinfecting of room surfaces." Replace with the following statement: "All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices."
- 4) As per the Agency letter of 3/30/10 propose revised Container Handling directions which are in agreement with a product such as yours with claims for public health pests. The container rinsate should not be emptied into the application equipment as this would produce an unknown dilution that would not be efficacious. The rinsate should be disposed of as pesticide waste.

## **General Comments**

Please include a copy of this letter with your revised amendment. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely.

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosures: Agency e-mail of 12/9/10, FAD-1

7510P:T.Lantz:12/30/2010:66171-7k



RISK ASSIGNMENT FORM
Il Division/Regulatory Management anch Il Antimicro

A		(	completed i	by Product	Manager						
PRODUCT	REVIEWER:		Traca			RMB	_I TEA	M31			
Descriptio	n of Action:	Lake	l Amer	dost		1 .	File Symbol/F				
Decision N	10.440203	Submission	No. 88/9	716	Fee for	Service Ad	tion Code:				
FQPA Action	on Code: 302	Non-FQPA	Action Co	de:	PRI	A FEE AMO	OUNT: \$				
	307	MONTH		DAY			YEAR				
APPLICAT	ION DATE	9	/			2010					
EPA PIN D	ATE	9	10			2010					
DATE PM R FRONT END	ECEIVED FROM						2010				
Date sent	to Reviewer						2010	M E			
DATE SEN	T TO SCIENCE						2010				
DATE REC SCIENCE	EIVED FROM										
PHADUE	DATE	G l	8	90	THE REAL PROPERTY.	OTIATED DATE					
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environme Fate	ntal E	ASSB cological ffects	RASSB Chronic Toxicology	RASSB Exposure/ Residue			
COMMENT	s: Jupil	Amportan Does +	A Need	le data	comp?	Trag	ast stamped Compas Agency of	6/24/09 reto letter 3/30/10			
ATTACHME	ENTS: -LABELI	NG [	J-CSF(S)	□-DAT	4	□-ОТН	ERS				
DATE FEE	PAID:		RESPON	NSE CODE:		RESPO	NSE DATE:				
	4 3901	7% 26%			(307)	te ? Either or se PRI					

# Fee for Service

{881916<~

This package includes the following	for Division
<ul><li>New Registration</li><li>Amendment</li><li>Studies?</li><li>Fee Waiver?</li><li>volpay % Reduction:</li></ul>	<ul><li>AD</li><li>BPPD</li><li>RD</li><li>Risk Mgr. 31</li></ul>
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	881916 66171-7 9/10/2010
This item is NOT subject to	to FFS action.
Action Code:  Requested:  Granted:  Amount Due: \$	Parent/Child Decisions:
inert Cleared for interided Use	Uncleared Inert in Product
Reviewer: 1eam 3	Date: 09/10/10
Remarks:	,

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum, kill of gram negative and gram positive microorganisms, SYNERGIZE provides effective disinfecting and cleaning in one operation, SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum. chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Berns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

#### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and screpers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain In contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



# SYNERGIZE

## **CLEANER - DISINFECTANT**

STAPHYLOCIDAL / PSEUDOMONACIDAL SALMONELLACIDAL / ASPERGILLOCIDAL / VIROCIDAL\* FUNGICIDAL / DEODORANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment. Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes, This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl I	benzyl ammonium chloride28.00%
Glutaraldehyde	7.00%
Inert Ingredients:	67.00%
TOTAL	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

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EPA Reg. No. EPA Est. Patent Number:		•	•		•	• 66171	T)	001	66171 71-CA-00 5,891,92

Batch No:

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#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law, If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for quidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two

General: Consult Federal, State or local disposal authorities for approved alteri

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, ovsters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### **FIRST AID**

IF IN EYES: Hold eye opan and rinse slowly and gently with water for 15-20 min remove contact lenses, if present, after the first 5 minutes, then continue rinsing evi a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

## SYNERGIZE

#### HATCHERY ROOMS. INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

#### A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

#### B) INCUBATORS AND HATCHERS

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

#### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four (24) hours. After twenty-four (24) hours before it is repopulated with poultry or livestock.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they should be washed with detergent and water before use for poultry or livestock.

#### AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE should be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown should be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### Intermittent (Slug Dose) Method

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

#### Continuous Feed Method

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus furnigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2



Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com Page 2 of 2





## **DOT SHIPPING NAME**

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III



APR 1 2010



## EPA United States Office of Pesticide Programs Agency Office of Pesticide Programs

The Dow Chemical Company 1803 Building Midland, Mi 48674

Attention: Rhonda Vance-Moeser

Senior Regulatory Specialist

Subject: GLUTEX ™ GQ1 Sanitizer and Disinfectant

EPA Registration No. 464-700

Amendment Dated December 10, 2009

in the design of the control of the

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

## **Proposed Amendment**

- 1. Change the primary product name
- 2. Alternate brand name
- 3. Add a disinfectant claim
- 4. Delete the egg sanitization claim
- 5. Revise label language in response to the RED

### **General Comment**

The request to change the alternate brand name from UCARCIDE™ 14 Antimicrobial" to "GLUTEX™ GQ1 Sanitizer and Disinfectant" is acceptable.

A stamped copy of the "accepted" label and Efficacy Review is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell

Product Manager (33)

Regulatory Management Branch 1 Antimicrobials Division (7510P)

**Enclosure** 

GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

## GLUTEX™ GQ1 Sanitizer and Disinfectant

Active Ingredient: Glutaraldehyde......14.0%

Alkyl (C<sub>14</sub> 50%, C<sub>12</sub> 40%, C<sub>16</sub> 10%)....... 2.5%

dimethyl benzyl ammonium chloride

EPA Reg. No. 464-700

EPA Est. No. 10352-WV-2<sup>(A)</sup>; 464-WV-1<sup>(B)</sup> 10352-WV-1<sup>(C)</sup>

(A) 5 gallon pails in pallets; all drums, bulk

(B) Sample, 5 gallon pails less than full pallet

(C) Bulk Shipments

ACCEPTED with COMMENTS.

APR - 1 2010

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Under the Federal Insectickle, Carlo Fungicide, and Rodonticide Act as amended, for the pesticide Carlo Registered under EPA Reg. No. 464-700

## KEEP OUT OF REACH OF CHILDREN

## DANGER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## DANGER

Corrosive • Causes irreversible eye damage • Causes skin irritation • Harmful if inhaled. Harmful if swallowed • Harmful if absorbed through skin • Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals • Causes asthmatic signs and symptoms in hyper-reactive individuals • Do not get in eyes, on skin, on clothing • Avoid breathing vapor • Do not swallow • Wash thoroughly with soap and water after handling • Remove contaminated clothing and wash before reuse.

## Personal Protective Equipment

Applicators and other handlers must wear: goggles or face shield, long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves (such as butyl rubber) and chemical resistant apron.

## **User Safety Requirements**

Follow manufacturers' instructions for cleaning & maintaining PPE if no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

## **User Safety Recommendations**

Users must wash hands before eating, drinking, chewing gum, or using the toilet.

464.700

GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

ACCEPTED
with COMMENTS
EPA Letter Dated:
APR - 1 2010

Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling the production of gloves before removing. As soon as possible, wash the outside of gloves before removing. As soon as possible, wash the pesticide act as amended, for the pesticide, registered under EPA Reg. No.

## **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish, aquatic invertebrates, oysters and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

	FIRST AID
IF SWALLOWED	<ul> <li>If the person is fully alert and cooperative, have the person rinse mouth with plenty of water. have the patient drink 4 to 10 ounces (120-300 mL) of water or milk.</li> <li>Do not induce vomiting. Do not attempt mouth rinse if the person has respiratory distress, altered mental status, or nausea and vomiting.</li> <li>Call a physician and/or transport to emergency facility immediately. See Note to Physician.</li> </ul>
IF IN EYES	<ul> <li>Wash immediately and continuously with flowing water for at least 30 minutes.</li> <li>Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist.</li> <li>Call a poison control center or a doctor immediately for treatment advice.</li> </ul>
IF ON SKIN OR CLOTHING	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF INHALED	<ul> <li>Move person to fresh air</li> <li>If person is not breathing, call 911 or an ambulance, and then give artificial respiration preferably mouth to mouth if possible.</li> <li>Call a poison control center or a doctor for further treatment advice</li> </ul>
Have product contain treatment.	ner or label with you when calling a poison control center or doctor or going for
	HOT LINE NUMBER ~
TICLOS OF ANTE	MCDCENCY and any in life or appropriate involving this product call called

IN CASE OF AN EMERGENCY endangering life or property involving this product, call collect (989) 636-4400.

NOTE TO PHYSICIAN: Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or a doctor, or going for treatment.

GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

ACCEPTED with COMMENTS **EPA Letter Dated:** 

Under the Federal Insecticide,

STORAGE AND HANDLING

Fingicide, and Rodenticide Act as GLUTEX GO1 Sanitizer and Disinfectant is incompatible with many commonly forsted practicals of construction such as steel, galvanized iron, aluminum, tin, and zinc. GPETEX union EPA Reg. No. 464-700 Sanitizer and Disinfectant can be stored and handled in baked phenolic-lined steel. polyethylene, stainless steel, or reinforced epoxy-plastic equipment. This product freezes at about 27°F (-3°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8 °C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C).

A stainless steel centrifugal pump is suggested for transfer service. Spiral-wound stainless steel with TEFLON® Polymer is suitable for gaskets and packing.

Handle in a well-ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

The product in its undiluted form must not be used in a spray, fogging or aerosol application.

## STORAGE AND DISPOSAL

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal** 

Option to use for labels on nonrefillable rigid containers of all sizes

Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Option to use for labels on refillable rigid tote containers

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning of the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean container before final disposal, empty contents into application equipment and triple rinse. Pour or pump rinsate into application equipment or rinsate collection system. Then offer for recycling if available, or puncture and dispose of in sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS/ RECIRCULATING COOLING AND PROCESS WATER SYSTEMS

This product may be used only in industrial air washers and air washer systems which have mist-eliminating components.

GLUTEX GQ1 Sanitizer and Disinfectant should be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as the basin area. Addition may be made intermittently (SLUG DOSE) or continuously. Badly fouled systems can be shock treated with GLUTEX GQ1 Sanitizer and Disinfectant. Under these conditions, blowdown should be discontinued for up to 24 hours.

GLUTEX GQ1 Sanitizer and Disinfectant can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (where approved for compatibility by the membrane manufacturer) and associated distribution systems.

## Intermittent (Slug Dose) Method

Initial Dose: When the system is noticeably fouled, apply 4.2 to 8.5 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.7 to 4.2 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per 100 gallons of water in the system weekly or as needed to maintain control.

Badly fouled systems must be cleaned before treatment is begun.

## **Continuous Feed Method**

Initial Dose: When the system is noticeably fouled, apply 4.2 to 8.5 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per 100 gallons of water in the system.

Subsequent Dose: Maintain this treatment level by starting a continuous feed of 0.8 to 4.2 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per 100 gallons of water in the system per day.

Badly fouled systems must be cleaned before treatment is begun.

## SERVICE WATER AND AUXILIARY SYSTEMS

GLUTEX GQ1 Sanitizer and Disinfectant should be used at the same application rates, and in the same manner as described above. It should be added to the system at a recipt that will allow for uniform mixing throughout the system.

with COMMENTS EPA Letter Dated:

APR - 1 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 984-700 GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

## **HEAT TRANSFER SYSTEMS**

(Evaporative Condensers, Dairy Sweetwater Systems, Hydrostatic Sterilizers and Retorts, and Pasteurizers and Warmers)

GLUTEX GQ1 Sanitizer and Disinfectant should be used at the same application rates, and in the same manner as described above. It should be added to the system at a point of uniform mixing such as a basin area, sump area or other reservoir or collecting area from which the treated water will be circulated uniformly throughout the system.

## INDUSTRIAL WASTEWATER SYSTEMS

(Wastewater Systems, Wastewater Sludge and Wastewater Holding Tanks) GLUTEX GQ1 Sanitizer and Disinfectant should be added to a wastewater system or sludge at a convenient point of uniform mixing such as the digester. Add 200 to 975 fluid ounces (1.6 to 7.6 gallons) (1,600 to 7,600 ppm product) of GLUTEX GQ1 Sanitizer and Disinfectant per 1,000 gallons of wastewater or sludge.

## PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS

GLUTEX GQ1 Sanitizer and Disinfectant should be added to the paper making system at a point of uniform mixing such as the beaters, broke chest pump, save-all tank, or white-water tank.

Initial Dose: When the system is noticeably contaminated, add 1.5 to 9.0 lbs of GLUTEX GQ1 Sanitizer and Disinfectant per ton or 0.76 to 4.5 Kg of GLUTEX GQ1 Sanitizer and Disinfectant per metric ton of pulp or paper (dry basis) as a slug dose. Repeat until control is achieved. Heavily fouled systems should be boiled out prior to initial treatment.

Subsequent Dose: When microbial control is evident, add 0.9 to 6.0 lbs of GLUTEX GQ1 Sanitizer and Disinfectant per ton or 0.46 to 3.0 Kg of GLUTEX GQ1 Sanitizer and Disinfectant per metric ton of pulp or paper (dry basis) as a slug dose as necessary to maintain control.

## WATER BASED COATINGS FOR PAPER AND PAPERBOARD

NOTE: For use in non-food contact coatings only.

Use from 0.3 to 1.8 lbs. of GLUTEX GQ1 Sanitizer and Disinfectant per 1,000 lbs. of dry powder or 0.3 to 1.8 Kg of GLUTEX GQ1 Sanitizer and Disinfectant per metric ton of dry slurry to produce a concentration from 300 to 1,800 ppm as product (based on slurry solids) in the mixed slurry.

ACCEPTED
with COMMENTS
- EPA Letter Dated:

APPR -- 1 2000

Under the Federal Insecticide
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 464-700

GLUTEX™ GO1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

with COMMENTS EPA Letter Dated:

1 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as WATER FLOODS
GLUTEX GQ1 Sanitizer and Disinfectant should be added to a water from the appoint of registered under EPA Reg. No. 4444-100

**Initial Treatment:** When the system is noticeably contaminated, add 300 to 15,000 ppm GLUTEX GO1 Sanitizer and Disinfectant to the system (0.3 to 14.5 gallons GLUTEX GO1 Sanitizer and Disinfectant per 1,000 gallons flood water). Repeat until control is achieved. Subsequent Dose: When microbial control is evident, add 60 to 15,000 ppm GLUTEX GO1 Sanitizer and Disinfectant (0.06 to 14.5 gallons) GLUTEX GQ1 Sanitizer and Disinfectant per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

## FRAC FLUIDS

WATER FLOODS

## Not registered for this use in the State of California

GLUTEX GO1 Sanitizer and Disinfectant reduces bacterial contamination and degradation of fracturing fluids and gels used in oil and gas well stimulations. Add GLUTEX GO1 Sanitizer and Disinfectant to the frac water storage tanks or directly into the well head injection pipeline as the water is being pumped down-hole.

Dose Range: GLUTEX GO1 Sanitizer and Disinfectant should be added at a rate of 360 to 17,900 ppm (3.5 - 172.5 gallons per 10,000 gallons) depending on the degree of bacterial fouling in the source water.

## DRILLING, COMPLETION, AND WORKOVER FLUIDS

GLUTEX GO1 Sanitizer and Disinfectant should be added to a drilling fluid system at a point of uniform mixing such as the circulating mud tank.

Initial Treatment: Add 150 to 3,000 ppm GLUTEX GO1 Sanitizer and Disinfectant (0.6 to 12.2 gallons GLUTEX GQ1 Sanitizer and Disinfectant per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination.

Maintenance Dosage: Maintain a concentration of 150 to 3,000 ppm GLUTEX GQ1 Sanitizer and Disinfectant by adding 0.6 to 12.2 gallons of GLUTEX GQ1 Sanitizer and Disinfectant per 100 barrels of additional fluid, or as needed, depending on the severity of contamination.

### PACKER FLUIDS

GLUTEX GO1 Sanitizer and Disinfectant should be added to a packer fluid at a point of uniform mixing such as a circulating holding tank. Add 150 to 1,800 ppm GLUTEX GQ1 Sanitizer and Disinfectant (0.6 to 7.3 gallons GLUTEX GQ1 Sanitizer and Disinfectant per 100 barrels of fluid) to a freshly prepared fluid depending on the severity of contamination. Seal the treated packer fluid in the wall between the casing and production tube.

## OIL AND GAS PRODUCTION AND TRANSMISSION PIPELINE SYSTEMS

GLUTEX GO1 Sanitizer and Disinfectant should be added to an oil/gas production or transmission line via direct injection. The application should be conducted to ensure maximum distribution of GLUTEX GQ1 Sanitizer and Disinfectant throughout the entire internal pipeline surface by adding a sufficient amount of biocide to detect/measure a residual concentration at the back end of the pipeline system. Criteria for success of the treatment will be a reduction in

GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

bacterial counts and/or reduced corrosion rates. To facilitate application, it may be desirable to dilute the GLUTEX GQ1 Sanitizer and Disinfectant with an appropriate solvent immediately before use. The concentration in the solvent should not fall below an active concentration range of 500 to 5000 ppm based on the volume of water in the pipeline. Injections to the system should be weekly, or as needed to maintain control.

### GAS STORAGE WELLS AND SYSTEMS

Individual injection wells should be treated with sufficient quantity of GLUTEX GQ1 Sanitizer and Disinfectant to produce a concentration of 1,500 to 15,000 ppm GLUTEX GQ1 Sanitizer and Disinfectant when diluted by the water present in the formation.

Injection should take place before gas is injected (during the summer). Injections should be repeated yearly, or as needed to maintain control.

Individual drips should be treated with a sufficient quantity of GLUTEX GQ1 Sanitizer and Disinfectant to produce a concentration of 600 to 6,000 ppm GLUTEX GQ1 Sanitizer and Disinfectant when diluted by the water present in the drip. Injections should be repeated yearly, or as needed to maintain control.

## HYDROTESTING

Water used to hydrotest pipelines or vessels should contain 300 to 12,000 ppm GLUTEX GQ1 Sanitizer and Disinfectant (0.3 to 11.8 gallons GLUTEX GQ1 Sanitizer and Disinfectant per 1,000 gallons water), depending on water quality and length of time the equipment will remain idle.

## PIPELINE PIGGING AND SCRAPING OPERATIONS

Add GLUTEX GQ1 Sanitizer and Disinfectant to a slug of water immediately following the scraper (ideally this water volume can be kept to a minimum and contained between the scraper and a trailing pig). Sufficient GLUTEX GQ1 Sanitizer and Disinfectant should be added to produce a concentration of 0.3 to 3% (0.29 to 2.9 gallon GLUTEX GQ1 Sanitizer and Disinfectant per 100 gallons water), depending on the length of the pipeline and the severity of biofouling.

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR - 7 2010

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 464-700 GLUTEX™ GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

## DISINFECTING OR SANITIZING NON-FOOD CONTACT SURFACES, FARM, ANIMAL, AND POULTRY HOUSING FACILITIES AND EQUIPMENT

Not registered for this use in the State of California DO NOT USE THIS PRODUCT ON FOOD OR FEED

GLUTEX GQ1 Sanitizer and Disinfectant is suitable for use on a wide variety of surfaces including stainless steel, aluminum, painted concrete, plastic, and glazed tile.

## Disinfection

For disinfection against the following pathogens: Klebsiella pneumoniae, Escherichia coli, Pasturella multocida, Salmonella enterica, Campylobacter jejuni Clostridium perfringens Haemophilus paragallinarum, Mycoplasma hyopneumoniae, Mycoplasma gallisepticum, Staphylococcus aureus, Pseudomonas aeruginosa and Salmonella enterica and for the following viruses: Swine Influenza Virua (H1N1), Porcine parvovirus, Avian Infectious Laryngotracheitis Virus and Porcine Respiratory Reproductive Syndrome Virus prepare disinfection solution according to the following:

Disinfection solution preparation:

1. Mix 1 fluid ounce of GLUTEX GQ1 Sanitizer and Disinfectant per gallon of water (8 mls per liter) to produce a solution containing 0.13% total active ingredients.

2. Allow prepared solution to stand on surface for at least 10 minutes, or until thoroughly dried.

3. Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled

## Sanitization

For sanitization against the following pathogens: Klebsiella pneumoniae, Salmonella cholerasuis, Staphylococcus aureus, and Pseudomonas aeruginosa and for the following viruses: Infectious bursal disease, Avian influenza (H6N2 and H5N1), SARS-associated coronavirus, Porcine circovirus and fungus: Aspergillus fumigatus, prepare sanitizing solution accourding to the following:

Sanitizing solution preparation:

 Mix 0.45 to 1.8 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per gallon of water (3.5 to 14.1 milliliters per liter) to produce a solution containing 0.06 to 0.24% total active ingredients.

2. For application against *Porcine circovirus*, mix 0.9 to 2.2 fluid ounces of GLUTEX GQ1 Sanitizer and Disinfectant per gallon of water (6.9 to 17.3 milliliters per liter) to produce a solution containing 0.12 to 0.293% total active ingredients.

3. Allow to stand for at least five minutes, or until thoroughly dried.

4. Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled.

with COMMENTS

EPA Letter Dated:

APR - 1 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 424-700

GLUTEX<sup>TM</sup> GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

#### Farm Equipment and Animal Housing Buildings

(Poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)

- 1. Remove all poultry and other animals and feed from the premises. Remove all portable equipment and empty all feeders and water troughs. If not removed, all treated feeders and waterers must be thoroughly rinsed with potable water prior to re-use.
- 2. Remove all litter and manure from floors and other surfaces.
- 3. Prepare either disinfection or sanitizing solution depending upon the organisms being treated by mixing the appropriate amount of GLUTEX GQ1 Sanitizer and Disinfectant with water. Refer to solution preparation above.
- 4. Using suitable commercially available equipment, saturate all surfaces with the prepared solution. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
- 5. Allow to stand for at least 5 minutes for sanitization or 10 minutes for disinfection.
- 6. Ventilate enclosed spaces.
- 7. Do not repopulate with poultry or other animals, or use equipment until treatment has been absorbed or dried.

#### Hatchers, Setters, and Chick Processing Facilities

Not for treatment of hatchers which contain chicks/eggs.

- 1. For disinfection or sanitizing of environmental surfaces prior to introduction of eggs: Remove all animals and feed from premises/vehicles and enclosures. Clean out feathers, fluff, or other debris.
- 2. Prepare either disinfection or sanitizing solution depending upon the organisms being treated by mixing the appropriate amount of GLUTEX GQ1 Sanitizer and Disinfectant with water. Refer to solution preparation above.
- 3. Thoroughly saturate all surfaces with the prepared solution. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
- 4. Allow to stand for at least 5 minutes for sanitization or 10 minutes for disinfection.
- 5. Ventilate thoroughly before reuse.
- 6. Note: for treatment of air and surfaces in high humidity hatchers and setters with water spray cooling: Fog or atomize this solution into setters or hatchers, using appropriate application equipment. Fogging of poultry houses should only be done in such a way that the operator is outside the poultry house when applying the fog. Wait at least 3 hours before re-entry after application
- 7. Note: For treatment of air and surfaces in low humidity hatchers with chilled coil cooling: Fog or atomize this product using appropriate application equipment. Fogging of poultry houses should only be done in such a way that the operator is outside the poultry house when applying the fog. Wait at least 3 hours before re-entry after application.

ACCEPTED
with COMMENTS
EPA Letter Dated:
APR - 1 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 3464-700 GLUTEX<sup>TM</sup> GO1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

#### Trays, Racks, Carts, Chick Boxes, Cages, and other Hard Surfaces:

1: Remove all filth and heavy debris from surfaces by scraping or washing.

2. Prepare either disinfection or sanitizing solution depending upon the organisms being treated by mixing the appropriate amount of GLUTEX GQ1 Sanitizer and Disinfectant with water Refer to solution preparation above.

3. Apply by spraying or immersion, and allow to drain and air-dry. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

4. Allow to stand for at least 5 minutes for sanitization or 10 minutes or for longer for disinfection.

5. Ventilate enclosed spaces.

6. Do not repopulate with poultry or other animals, or use equipment until treatment has been absorbed or dried.

#### Trucks and other Vehicles

1. Remove all filth and heavy debris from surfaces by scraping or washing.

2. Prepare either disinfection or sanitizing solution depending upon the organisms being treated by mixing the appropriate amount of GLUTEX GQ1 Sanitizer and Disinfectant with water Refer to solution preparation above.

3. Apply by spraying or immersion, and allow to air-dry.

4. Allow to stand for at least 5 minutes for sanitization or 10 minutes or for longer for disinfection.

5. Ventilate enclosed spaces.

6. Do not repopulate with poultry or other animals, or use equipment until treatment has been absorbed or dried.

#### SANITIZING NON-FOOD CONTACT DISINFECTING OR SURFACES. INDUSTRIAL EQUIPMENT AND BUILDINGS Not registered for this use in the State of California

1. Remove all heavy filth and soil deposits from surfaces using a suitable cleaner.

2. Prepare either disinfection or sanitizing solution by mixing the appropriate amount of GLUTEX GQ1 Sanitizer and Disinfectant with water. Refer to solution preparation above.

3. Using suitable commercially available equipment, saturate all surfaces with the prepared solution. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

4. Allow to stand for at least 5 minutes for sanitization or 10 minutes or for longer for disinfection.

5. Ventilate enclosed spaces.

ACCEPTED 6. Do not repopulate with poultry or other animals, or use equipment until treatment of the company of the comp absorbed or dried. **EPA Letter Dated:** 

> Under the Federal Insecticios Fungicide, and Rodenticide act as amended, for the pesticide, registered under EPA Red. No.

GLUTEX<sup>TM</sup> GQ1 Sanitizer and Disinfectant FINAL MASTER LABEL December, 2009

NET Contents/Net Weight:

Container Size 260.8 gallons	Container Size 55 gallon	Container Size 5 gallon	Container Size 1 gallon	
Net Weight	Net Weight	Net Weight	Net Weight	
2,290 Pounds	470 Pounds	44 Pounds	8.6 Pounds	

LOT No.:

Produced For (used when product manufactured by contract manufacturer)

Dow Diamond TM
THE DOW CHEMICAL COMPANY
Midland, Michigan 48674
989-636-4400

Trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR - 1 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 444-700

# ENVIRONMENTAL PROTECTION AGENCY PESTICIDES OFFICE WASHINGTON, D.C., 20250

May 16, 1972

Pesticides Regulation Division

#### FAD-1 Enclosure

FOR ALGICIDES AND SLIMICIDES IN COOLING WATER UNDER
THE FEDERAL INSECTICIDE, FUNGICIDE, AND
RODENTICIDE ACT

#### I. Purpose

This is a guide and source of information for manufacturers of products intended for use in control of microbiological slimes in cooling water systems. Such products are pesticides (economic poisons) and must be registered before they can be legally shipped in interstate commerce.

#### II. Definitions

Algicide, Bactericide, Fungicide - Any substance or mixture of substances which kills or effectively reduces the number of living algae, bacteria, or fungi in water. (Bactericide as defined herein is restricted to products used in "cooling water," as defined, and must not be related to products represented or defined as disinfectants).

Algistat, Bacteriostat, Fungistat - Any substance or mixture of substances which effectively controls or temporarily prevents the growth of algae, bacteria, or fungi.

Bacteria - See fungi.

Blowdown (Bleed-off) - Water discharged from the system to control concentrations of salts or other impurities in the circulating water. Blowdown is measured in gallons per minute.

Closed Recirculating Systems - Essentially all the water is continuously recycled and the heat is removed from the circulating water in a heat exchanger that may be cooled by air, mechanical refrigeration, or a separate open cooling water system.

Cooling Water - Water used for industrial service and comfort cooling purposes. Used for cooling purposes in once-through systems, open recirculating systems, or closed recirculating systems.

Fungi - All non-chlorophyll-bearing thallophytes (that is, all non-chlorophyll-bearing plants of a lower order than mosses and liverworts) as for example: molds, yeast, and bacteria.

Make-up Water - Water added to the circulating water system to replace water lost from the system due to blowdown (bleed-off), drift, evaporation,

leakage and overflow.

Microbiocide - Any substance or mixture of substances which effectively reduce the number of living microorganisms (algae, bacteria, and fungi). See also Algicide, Bactericide, Fungicide.

Microbiological Slime - An accumulation of microorganisms and their secretions plus embedded debris. The microorganisms associated with slime are algae, bacteria and fungi.

Microbiostat - See Algistat, Bacteriostat, Fungistat.

Once-through Systems - Water is taken from some primary source, used for cooling, and then discharged to waste or used for other purposes.

Open Recirculating Systems - A major portion of the water used for process cooling is continuously recycled to some type of evaporative cooling device, such as a cooling tower, to remove the heat picked up in the process and is then used again for process cooling.

#### III. Claims

Microbiological deposits interfere with the efficiency of cooling water systems. In the framework of cooling water systems, control of bacterial, fungal, or algal slime is taken to mean the maintenance of the microbial population at some acceptable level which will not materially affect the efficient operation of the system.

Broad claims for use such as "microbiocide," "microbiostat," "slimicides," and "microorganism control" are acceptable only when modified by, (1) naming the types of organisms (algae, bacteria, fungi) for which control is intended and, (2) naming the industrial or commercial recirculating water cooling systems, such as "industrial (and/or commercial) recirculating cooling water towers," "air washers" and/or "evaporative condensers." Terms such as "biocide" or "biostat" are unacceptable where only microorganism control is to be construed. Cidal claims are acceptable only where the product has been demonstrated to be capable of effectively reducing the number of living algae, bacteria or fungi. Static claims are to be made for products which have been demonstrated to provide temporary control or growth suppression of the stated types of organisms. The claim for a type of activity (cidal or static) must be related to each particular use claimed on the labeling.

#### Examples:

- A. Microbiocide for use in industrial recirculating cooling water towers to reduce the number of living algae, bacteria and fungi.
- B. Microbiostat (microorganism control) for use in industrial recirculating cooling water towers to control the growth of algae, bacteria and fungi.

#### Directions for Use

Directions for use must include the following:

- 1. Where in the system the product is to be applied. For example: at a point in the system where it will be uniformly mixed.
- When the product should be applied (such as when the system is in jeopardy of becoming affected or after cleaning systems whose efficiency is already impaired).
- 3. The dosage and method of application. The dosage rate for solid products must be specified as weight of product per unit volume of water. The labels of solid products in the form of tablets, briquettes or other uniformly sized shapes should state the weight of each such unit.

The dosage rate for liquid products should be specified as fluid volume of product per unit volume of water. This rate may also be expressed in parts per million of the product following the fluid volume rate. The product weight per gallon must be shown on the application. If liquid products are added on a weight basis, the product weight per gallon must be shown on the label.

- 4. The method of application or pattern of use includes an initial application which may be repeated, followed by subsequent applications. The initial dosage range is for the purpose of controlling noticeable contamination, to satisfy the demand of the system which may have extensive but not noticeable contamination, or to rapidly develop a desired level of toxicant in the system water. The subsequent dosage range is for the purpose of inhibiting the growth of microorganisms remaining in the system or subsequently introduced into the system. In case of reinfestation of the system to a noticeable extent, the initial dosage range should be applied until control is again evident. Examples of various methods of application or patterns of use are given below.
  - (a) Intermittent or "Slug Method" The directions must stipulate an initial dose range of relatively high product concentrations, to obtain control of obvious microbial contamination. When microbial control is evident, a subsequent dose range, of relatively lower product concentrations, must be stated. The usual time interval between doses must be stated provided that this is further qualified with the phrase "or as needed to maintain control." The label must not claim maintenance of any particular concentration. Example: Initial Dose: When the system is noticeably fouled, apply

*	per [unit volume] of water in the system. Repeat until control is achieved.
	Subsequent Dose: When microbial control is evident, add to[fluid volume or unit weight] of[product name] per[unit volume] of water in the system everydays (weekly), or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.
	(b) Modified Intermittent Method - This is similar to the intermittent or slug method (a) except that the interval between treatments is based on the time for a stated fraction of the system water to be lost by blowdown. This method of application may permit a claim to maintain the concentration within stated maximal and minimal limits. Example:
	Initial Dose: When the system is just noticeably fouled, apply to[fluid volume or unit weight] of[product name] per[unit volume] of water in the system. Apply half [or 1/3, 1/4, or 1/5] of this initial dose when half [or 1/3, 1/4, or 1/5] of the water in the system has been lost by blowdown.
	Subsequent Dose: When control of microbial growth is evident, apply to [fluid volume or unit weight] of [product name] per [unit volume] of water in the system. Apply half [or 1/3, 1/4, or 1/5] of the subsequent dose when half [or 1/3, 1/4, or 1/5] of the water in the system has been by lost by blowdown.
	Badly fouled systems must be cleaned before treatment is begun.
)	Continuous Feed Method - The label should specify an initial slug dose based on the volume of water in the cooling system. The initial slug dose is required to establish an initial product concentration. For volatile products, continuous feed doses are based on total make-up water. Continuous feed dosage rates for non-volatile products are expressed as amount of product to be applied per stated volume of water lost by blowdown. The claim to maintain a concentration in the system may be made for the continuous feed method of application. Example
	Initial Dose: When the system is just noticeably fouled, apply  [fluid volume or unit weight] of [product name] per  [unit volume] of water in the system.
	Subsequent Dose: Maintain this treatment level by starting a continuous feed of [fluid volume or unit weight] of [product name] per [unit volume] of water lost by blowdown. Badly fouled systems must be cleaned before treatment is begun.

(d) Briquettes or Tablets may be considered to be a slug dose method of application. Data must be submitted showing the rates of dissolution of the product in waters at various temperatures and flow rates.

#### V. Data Requirements

- Laboratory data must be submitted to show the presumptive effectiveness of the product against algae, bacteria and/or fungi. These data may be minimum inhibitory concentration determinations. If the product contains a new chemical or chemicals, the antimicrobial activity, if any, of each such ingredient must be determined and reported against algae, bacteria and/or fungi.
- 2. Based on the data obtained in item 1, application must be made for an Experimental Permit and the product tested to determine a dosage range and pattern of use in water systems in which the product is intended to be used. The following test criteria should be considered:
  - (a) Tests must be made in at least 2 different climatic locations for a period of not less than 30 days. Test systems should be representative of the more severe conditions that the product is intended to control.
  - (b) Reports must include (but are not limited to) the following:
    - (1) The dosage applied at each treatment.
    - (2) The interval between treatments.
    - (3) Visual or other suitable ratings of the nature and amount of microbial growth. The rating scale should be defined, and the commercially acceptable level indicated.
    - (4) The total volume of the system.
    - (5) The percent blowdown, if applicable, per unit of time.
    - (6) The volume of make-up water added to the system during the test period.

- (7) Water characteristics such as pH, hardness, temperatures and identification of any anticorrosion inhibitors together with an estimate of their concentration in the system and identification of any antimicrobial chemicals that were used immediately prior to or during the test period.
- (8) All appropriate engineering data reflecting efficient operation of the system, such as heat transfer readings, head pressures, down time, etc. Base line data on each parameter used is necessary for comparative purposes.
- (9) Bacterial counts before and after treatment are required for determining the interval(s) between product dosages and whether or not a product is cidal or static. Note: Counts must be accompanied by engineering data as indicated in (8) above submitted in support of static effects.
- (10) Where, when and by whom the tests were conducted.

105 (v) The physical characteristics of the swimming pool water, including temperature, color, and clarity. (vi) Materological data, including air temperature, rainfall, and number of hours of sunlight, which may affect results. (2) Simulated pools. In lieu of the in-use tests, acceptable confirming data may also be obtained from tests conducted in simulated swimming pools artificially inoculated with algae. Consultation with the Agency about procedures and test species prior to undertaking these tests is strongly recommended. An acceptable simulated swimming pool method is provided in § 92-20(f) Method for Evaluating Algicides in Simulated Swimming Pools. (d) Suggested performance standards. (1) Pure-culture tests. For pure-culture testing, the acceptable level of performance is 70% control of algae in primary cultures for 3 weeks. (See § 92-20(e)). (2) In-use pools. For in-use swimming pool testing, the level of performance should equal or exceed that of a standard chlorine treatment. (3) Simulated pools. For simulated-swimming pool testing, the acceptable level of performance must be equal to or better than a chilorine standard at 1.0 to 1.5 ppm for isocyanuric acid-stabilized pools or at 0.6 to 1.0 ppm for non-stablized pools. (See § 92-20(f)). § 92-4 Industrial cooling water microbicides. (a) Scope. Products intended to control microbiological slimes in cooling water systems include those with algicidal, bactericidal, and fungicidal activity. Microbiological slimes consist of microorganisms (algae, bactaria, and/or fungi) and their secretions, plus embedded debris. (b) Definitions. The following definitions and explanations are particularly pertinent to the understanding of this section: (1) Bactericide. As used in this section, this term is restricted to . products used in cooling water for controlling bacterial slime, and must not be construed to include products represented or defined as disinfectants described in §§ 91 (Efficacy of Antimicrobial Agents). (2) Blowdown (bleed-off). This term means: water discharged from the system to control concentrations of salts or other impurities in the circulating water. -- Blowdown is measured in-volume per unit time. (3) Closed recirculating systems. This term means: a system of continuously recirculating water in a heat exchanger that may be cooled by air, mechanical refrigeration, or a separate open cooling-water system. 82

- water system to replace that lost because of blowdown (bleed-off), drift,
- substance or mixture of substances which effectively reduces the number of
- (6) Once-through systems. This term refers to systems where water is taken from some primary source, used for cooling, and then either discharged
- (7) Open recirculating systems. This term refers to systems where a major portion of the water used for process cooling is continuously recycled to some type of evaporative cooling device, such as a cooling tower, to remove the heat picked up in the process, and is then used again for process
- (c) Data guidance. (1) Laboratory testing. Laboratory data should be submitted to show presumptive effectiveness of the product in controlling algae, bacteria, fungi or combinations thereof when field testing is used
- (i) Standard Laboratory techniques should be used to determine minimum concentrations of the product which will kill or prevent growth of target organisms. The viability of pure culture algae should also be determined by a technique involving subculture into untrested medium. (See § 92-20(e)). Laboratory evaluation of bacteria and fungi shall consist of determining minimum effective static and cidal concentrations of product on unshaken liquid cultures.
- (ii) The following test species should be employed: bacteria: Pseudomonas spp. and Bacillus mycoides (ATCC); fungi: Aspergillus niger (ATCC); algae: Chlorella pyrenoidosa, Euglena gracilis, and Scenedesmus obliques. (For algae, see 92-20(e) for methods and growth media).
- (d) Field testing. Tests should be made in at least 2 different climatic locations for a period of not less than 30 days. Test systems should be representative of the more severe conditions that the product is intended to control.
  - (1) Reports should include, but are not limited to, the following:
- (i) Dosage applied at each treatment and contact period necessary for control of organisms.
  - (ii) Interval between treatments.
- (iii) Visual or other suitable ratings of the nature and amount of microbial growth. The rating scale shall be defined, and the commercially acceptable level of control should be indicated.
  - (iv) Total volume in the system.



Re: Synergize 66171-7 Tracy Lantz to: Gary E. Gaumer Cc: Velma Noble

12/29/2010 03:18 PM

Tomorrow is the absolute last day I can accept these forms. If not received tomorrow I will not have enough time to review and still meet my deadline. Without these forms the application is unacceptable. You will recall we began discussing this issue 3 weeks ago.

Your reply to our 12/20 letter must be sent through the mail to front end processing.

Tracy Lantz

Regulatory Team 31
Antimicrobials Division

Drag Lante

**U.S. Environmental Protection Agency** 

Phone: (703) 308-6415 FAX: (703) 308-8481

"Gary E. Gaumer"

Hello Tracy, Sorry for the delay in replying. We...

12/29/2010 03:01:15 PM

From:

"Gary E. Gaumer" < gegaumer@preserveinc.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Date: Subject: 12/29/2010 03:01 PM Re: Synergize 66171-7

Hello Tracy,

Sorry for the delay in replying. We will try to get this to you tomorrow.

We received the 12/20 letter requesting changes to the CSFs that we have submitted. Are the changes something we can email to you, or do they have to be mailed?

GG

On Dec 21, 2010, at 3:26 PM, Lantz.Tracy@epamail.epa.gov wrote:

- > I have not yet received your data compensation forms (described below.)
- > These forms are needed to continue my review of your amendment.
- > Please send these forms via e-mail by 12/29/10. You may scan the forms
- > and send via e-mail as pdf files.
- > Thanks
- > (Embedded image moved to file: pic16060.jpg)

>

```
"gegaumer@preserveinc.com" <gegaumer@preserveinc.com>
   From:
               Tracy Lantz/DC/USEPA/US@EPA
   To:
               12/10/2010 12:04 PM
   Date:
   Subject:
               Re: Synergize 66171-7
> I believe we do have all of the studies..
> Thank you for your help and patience.
> Have a great weekend!
> GG
> On Dec 10, 2010, at 9:00 AM, Lantz.Tracy@epamail.epa.gov wrote:
>> You would not offer compensation if you have studies to support all of
>> the data requirements.
>> I am guessing that you may not have studies for all requirements.
>> Many of our registrants do not have all 6 acute tox studies. They are
>> usually missing acute inhalation.
>> If you do not have this study you will need to offer compensation.
>> (Embedded image moved to file: pic20600.jpg)
>>
>>
>>
>>
               "gegaumer@preserveinc.com" <gegaumer@preserveinc.com>
>>
               Tracy Lantz/DC/USEPA/US@EPA
>> To:
>>
>> Date:
               12/10/2010 11:44 AM
>>
>> Subject: Re: Synergize 66171-7
>>
>>
>>
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>>
>>
>> That makes sense...
>> Are we required to offer compensation, If we have generated all the
>> required data?
>>
>> GG
>>
>>
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>> On Dec 10, 2010, at 6:35 AM, Lantz.Tracy@epamail.epa.gov wrote:
>>> No, you don't resubmit them. You cite them by MRID on the forms.
>>> All of this data compensation is required every time you submit an
>>> amendment with new data or when you do something new such as add a
>>> use pattern (such at this application) or increase a rate if it
>> differs
>>> from what we have already accepted for other products.
>>>
>>> (Embedded image moved to file: pic16541.jpg)
>>>
>>>
>>>
>>>
                "gegaumer@preserveinc.com" < gegaumer@preserveinc.com>
>>> From:
>>
>>>
>>> To:
                Tracy Lantz/DC/USEPA/US@EPA
>>
>>>
                12/09/2010 08:46 PM
>>> Date:
>>
>>>
               Re: Synergize 66171-7
>>> Subject:
>>
>>>
>>>
>>>
>>>
>>>
>>>
>>> Thank you for the clarification.
>>>
>>> All the studies you reference, have already been submitted, when we
>>> originally submitted Synergize for registration. We wouldn't need to
>>> resubmit them would we?
>>>
>>> GG
>>>
>>>
>>> On Dec 9, 2010, at 4:02 PM, Lantz.Tracy@epamail.epa.gov wrote:
>>>> Generic data (data requirements as per the REDs for ADBAC and Glut)
>>> will
>>>> be satisfied with your formulator's exemption form.
>>>> Product specific requirements are chemistry data, group A and B, the
>> 6
>>> acute tox studies (primary eye, primary skin, acute dermal, acute
>>> oral,
>>>> acute inhalation, and dermal sensitization) as well as efficacy data
>>>> support all of the public health claims on your label. This is data
>>>> your formulation as packaged for sale. If you don't have all of
>> these
>>>> studies you need to get permission to cite a study for a product
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>>>> like yours or you need to use the cite all option and offer to pay
>>>> everyone with your AIs who has provided that study to the Agency for
>>>> review.
>>>>
>>>> (Embedded image moved to file: pic00041.jpg)
>>>>
>>>>
                 "Gary E. Gaumer" < gegaumer@preserveinc.com>
>>>> From:
>>>>
                 Tracy Lantz/DC/USEPA/US@EPA
>>>> To:
>>>
>>>>
>>>> Date:
                 12/09/2010 06:56 PM
>>>
>>>>
>>>> Subject:
                Re: Synergize 66171-7
>>>
>>>>
>>>>
>>>>
>>>>
>>>>
>>>> Sorry for being dense, but could you please provide me a list of all
>>>> data required assuming we are purchasing from a registered source?
>>>>
>>>> Thanks,
>>>>
>>>> GG
>>>>
>>>> On Dec 9, 2010, at 3:26 PM, Lantz.Tracy@epamail.epa.gov wrote:
>>>> In order to support the generic data requirements you would only
>> need
>>>> to
>>>> provide the formulator's exemption statement.
>>>> You must still support the product specific data requirements as
>>>> described in my previous e-mail.
>>>> (Embedded image moved to file: pic31230.jpg)
>>>>>
>>>>>
>>>>>
                  "Gary E. Gaumer" <gegaumer@preserveinc.com>
>>>> From:
>>>>
>>>>>
>>>> To:
                  Tracy Lantz/DC/USEPA/US@EPA
                  12/09/2010 06:16 PM
>>>> Date:
               Re: Synergize 66171-7
>>>> Subject:
>>>>
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>>>>> >>>>> >>>>> >>>>> >>>>> >>>>> >>>> Hi Tracy, >>>>> >>>> Thank you for the note... >>>> We are purchasing the raw material from register sources, so am I >>>> correct in reading your email that the only thing we need to send >>>> this time is a formulator's exemption? If so, we will get it out > to >>>> you >>>> the first part of next week. >>>>> >>>> As always, thank you. >>>>> >>>> GG >>>> >>>>> >>>> On Dec 9, 2010, at 3:03 PM, Lantz.Tracy@epamail.epa.gov wrote: >>>>> I have been reviewing your label amendment dated 9/1/2010. >>>>> You have proposed adding a new use for this product (industrial >>>>> treatment) which is significantly different from other uses on >>>>> label. >>>>> >>>>> Although this use is not new for either of the AI's and seems to >>>>> within the range of previously accepted dosage rates for this use, >>>> this >>>>> use is new for this product and thus data compensation is >>>>> When data compensation is required the time frame for review >>>>> to 120 days such that the Agency has additional time to review the >>>> data >>>>> compensation. Thus this application is due out on 1/8/2011. >>>>> In order for me to continue to work toward approving this label >>>>> amendment, submit data compensation for product specific as well > as >>>>> generic data requirements. If you are purchasing registered >> sources >>>>> of >>>>> active ingredients you may submit a formulator's exemption >> statement >>>>> to >>>>> cover the generic data requirements. If you are not purchasing >>>>> registered sources, you must submit a certification with respect >>>>> citation of data form along with an internal and public file copy >> of >>>> the >>>>> completed data matrix for each active ingredient. In addition to

88

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Re: Synergize 66171-7

Tracy Lantz to: gegaumer@preserveinc.com

12/21/2010 06:26 PM

I have not yet received your data compensation forms (described below.) These forms are needed to continue my review of your amendment.

Please send these forms via e-mail by 12/29/10. You may scan the forms and send via e-mail as pdf files.

Thanks

**Tracy Lantz** 

Regulatory Team 31
Antimicrobials Division

Drag Lant

**U. S. Environmental Protection Agency** 

Phone: (703) 308-6415 FAX: (703) 308-8481

"gegaumer@preserveinc.com"

I believe we do have all of the studi ...

12/10/2010 12:04:28 PM

From:

"gegaumer@preserveinc.com" < gegaumer@preserveinc.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Date: Subject: 12/10/2010 12:04 PM Re: Synergize 66171-7

I believe we do have all of the studies ..

Thank you for your help and patience.

Have a great weekend!

GG

On Dec 10, 2010, at 9:00 AM, Lantz.Tracy@epamail.epa.gov wrote:

> You would not offer compensation if you have studies to support all of > the data requirements.

> I am guessing that you may not have studies for all requirements.

> Many of our registrants do not have all 6 acute tox studies. They are > usually missing acute inhalation.

> If you do not have this study you will need to offer compensation.

> (Embedded image moved to file: pic20600.jpg)

> >

From:

"gegaumer@preserveinc.com" <gegaumer@preserveinc.com>

> To:

Tracy Lantz/DC/USEPA/US@EPA

>

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Date:
               12/10/2010 11:44 AM
               Re: Synergize 66171-7
   Subject:
>
>
>
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>> use pattern (such at this application) or increase a rate if it
> differs
>> from what we have already accepted for other products.
>> (Embedded image moved to file: pic16541.jpg)
>>
>>
>>
               "gegaumer@preserveinc.com" < gegaumer@preserveinc.com>
>> From:
>>
               Tracy Lantz/DC/USEPA/US@EPA
>> To:
>>
               12/09/2010 08:46 PM
>> Date:
>>
>> Subject:
              Re: Synergize 66171-7
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>>> To:
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>>>
                12/09/2010 06:56 PM
>>> Date:
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>>> Subject:
               Re: Synergize 66171-7
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>>>> (Embedded image moved to file: pic31230.jpg)
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92

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>>>>
                 12/09/2010 06:16 PM
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12/10/2010 12:00 PM

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Tracy Lantz

Regulatory Team 31
Antimicrobials Division

**U.S. Environmental Protection Agency** 

Phone: (703) 308-6415 FAX: (703) 308-8481

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12/10/2010 11:44:36 AM

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"gegaumer@preserveinc.com" < gegaumer@preserveinc.com>

To:

Tracy Lantz/DC/USEPA/US@EPA

Date: Subject: 12/10/2010 11:44 AM Re: Synergize 66171-7

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Synergize 66171-7 Tracy Lantz to: Gary E. Gaumer Cc: Velma Noble

12/09/2010 06:03 PM

I have been reviewing your label amendment dated 9/1/2010.

You have proposed adding a new use for this product (industrial water treatment) which is significantly different from other uses on this label.

Although this use is not new for either of the Al's and seems to fall within the range of previously accepted dosage rates for this use, this use is new for this product and thus data compensation is required. When data compensation is required the time frame for review increases to 120 days such that the Agency has additional time to review the data compensation. Thus this application is due out on 1/8/2011.

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Please submit this information as soon as possible so that I can continue to move forward with this review of your label amendment.

Thanks,

Tracy Lantz



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 13, 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

GARY GAUMER PRESERVE INTERNATIONAL PO Box 17003 RENO, NV 89511-

PRODUCT NAME: SYNERGIZE

COMPANY NAME: PRESERVE INTERNATIONAL

**OPP IDENTIFICATION NUMBER:** 

EPA FILE SYMBOL: 66171-7 EPA RECEIPT DATE: 09/10/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

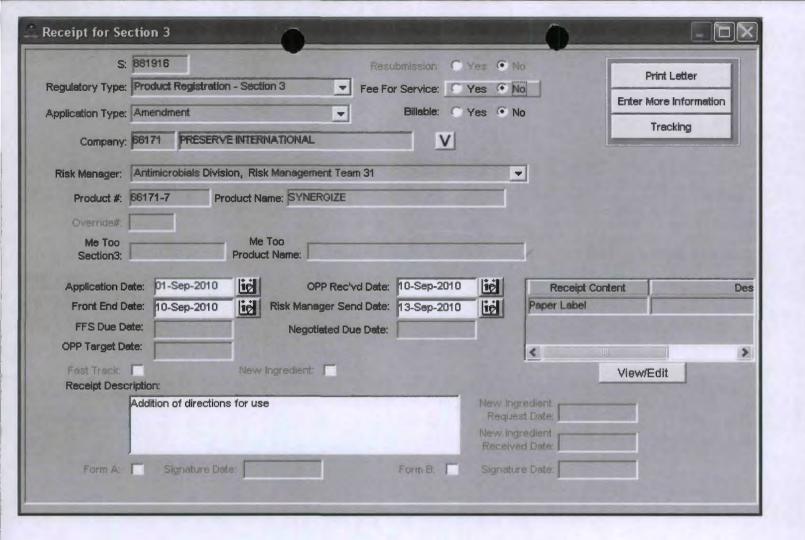
During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

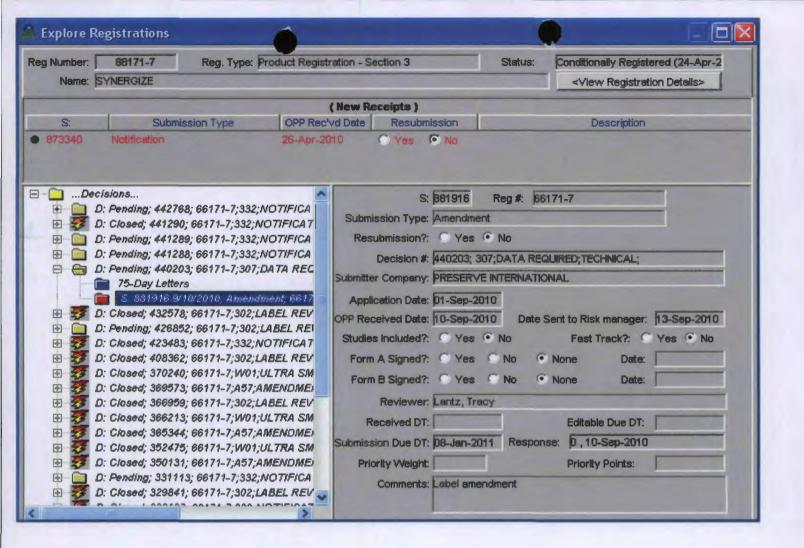
If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

P. K. Moone

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division







World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

September 1, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Synergize, USEPA Registration Number 66171-7

Dear Ms Noble:

Preserve International submits this amendment package for the addition of directions for use in air washers and industrial scrubbing systems / recirculating cooling and process water systems. In addition, we have added some descriptive headings at the top of the center panel. We have highlighted both sections that were added.

For your review, we have included a copy of Dow Chemical Company's Glutex label demonstrating the EPA's prior registration of this use in a product with similar ingredients. Again, we have highlighted the pertinent section.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President

Please read instructions on	reverse before completing for	orm.		Form Ap	pevoro				expires 2-28-9	
Environmental Protecti Washington, DC 20			n Agency Am				egistration mendment ther		OPP Identifier Number	
	Арр	licatio	on for Pestic	ide - Sec	tion	ī		1		
1. Company/Product Number	66171-7			Product Man			3. Pr	None None	sification Restricted	
4. Company/Product (Name	Synergize		PM# 31							
5. Name and Address of Ap Preserve International PO Box 17003 Reno, NV 89511	plicant (Include ZIP Code)		(b)(i), to: EPA	my product Reg. No	is sim					
	710 0 11011 0001000	-	Section -	uct Name			•• •			
Notification - Explain  Explanation: Use additio	below.  nel page(s) if necessary. (For air washers and industrial	or section	n I and Section II.) g systems / recircul	Agency lett "Me Too"  Other - Exp	ter dat Applica	ation. plow.	***	n addition, we	have added	
			Section -	111						
1. Material This Product Wi	li Be Packaged In:									
Child-Resistant Packaging Yes No Certification must be submitted		, per ntainer	Water Soluble Yes No If "Yes" Package wgt	No. per containe	r	2. Type of	Metal Plastic Glass Paper	Specify)	O.	
3. Location of Net Contents			teil Conteiner 50g,55g,30g,15g,	5g,4x1g	5. Lo	cation of La		ons		
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stence	raph glued iled	<b>✓</b> Othe	r Sie	eve				
			Section -	IV				••••		
1. Contact Point (Complete	items directly below for ide	ntificetio	on of individual to l	be contacted,	if nec	essary, to p	rocess this	application.)		
Name Gary Gaumer			Title President				Telephon 775-853-	9776 (Includ	e Area Code)	
•	ments I have mede on this f y knowlingly false or misle		ell attachments th				•	6. Date Apr Received		

3. Title President

5. Date

2. Signature

4. Typed Name Gary Gaumer

September 1, 2010

### ATES ENVIRONMENTAL PROTECTIO

Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511

Subject:

Synergize

EPA Registration No.: 66171-7

Notification Dated: November 22, 2010 EPA Receipt Date: November 24, 2010

Dear Mr. Gaumer,

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRRA), as amended and PR Notice 98-10.

Notification to add Alternate Formulations

Based on a review of the submitted information this notification is unacceptable due to the concerns listed below. You have submitted two alternate Confidential Statements of Formulations (CSFs) dated 11/22/10. A number or elements are missing from each CSF.

- 1) List the Reg. No. of this product; 66171-7 on each page of each CSF.
- 2) List the percent by weight of each component of each formulation. (column 13 b). Also list in column 13 b the nominal identifying it with "n =" for each component which is not supplied at 100% (each active ingredient,
  - 3) List the Reg. No. of the quaternary ammonium active ingredient source.
  - 4) List the total weight of each formulation.

Submit revised CSFs addressing the issues noted above. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

> Sincerely, Tray Lords Velma Noble. Product Manager (31). Regulatory management Branch I.

EPA Form	1320-1A (1/90)			Printed on Recycles	l Paper		OFFICI	E FILE COPY
DATE	12/20/10							
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## RISK ASSIGNMENT FORM Antimicrobial Division/Regulatory Management Branch II

A			Completed	by Product Ma	anager			
PRODUCT	REVIEWER:		Tracy		RMB	_I TEA	M31	
Description	of Action:	N	otific	ntri		File Symbol/F		
Decision No	. 442 768	Submission	No. 880	6777 F	ee for Service Ad	ction Code:		
FQPA Actio	n Code: 33	2 Non-FQPA	Action Co	de:	PRIA FEE AMO	OUNT: \$		
		MONTH		DAY		YEAR		
APPLICATIO	ON DATE	11	2	2		2010		
EPA PIN DA	TE	11	24	1		2010		
DATE PM RE FRONT END	CEIVED FROM					2010		
Date sent to	Reviewer					2010		
DATE SENT	TO SCIENCE					2010		
DATE RECE SCIENCE	IVED FROM			1 1 N 260				
PAN DUE D	ATE	12	24	2010	NEGOTIATED DUE DATE			
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/ Residue	
COMMENTS		icatm-	- 6in	e to T	Tray			
ATTACHME	NTS: -LABE	LING	J-CSF(S)	□-DATA	□-ОТН	ERS	T in	
DATE FEE P	AID:		RESPON	NSE CODE:	RESPO	NSE DATE:		



United States

#### **Environmental Protection Agency**

Washington, DC 20460

### Formulator's Exemption Statement

•	(40 CFR 152.85)
Applicant's Name and Address Preserve International	EPA File Symbol/Registration Number
PO Box 17003	66171-7
Reno, NV 89511	Product Name
• • • • • • • • • • • • • • • • • • • •	Syners, 22- Jensen
• • • •	Date of Confidential Statement of Formula (EPA Form 8570-4)
	11/22/10
• •	

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride

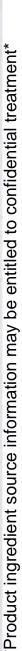
Glutaraldehyde

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
  - (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source			
Active Ingredient	Product Name	Registration Number	
Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride			
Glutaraldehyde			
Signature	Name and Title	Date	
150	Gary E. Gaumer	1/12/10	

EPA Form 8579-27 (Rev. 8-95)

White - EPA copy Yellow - Applicant copy





**\$EPA** 

United States

#### **Environmental Protection Agency**

Washington, DC 20460

### Formulator's Exemption Statement (40 CFR 152.85)

Applicant's	Name	and	Address
Preserve In	ternati	onal	
PO Box 170	003		
Reno, NV 8	9511		

EPA File Symbol/Registration Number

66171-7

Product Name

Synergize

Date of Confidential Statement of Formula | EPA Form 8570-4|

11/22/10

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Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride

Glutaraldehyde

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.
- (3) Indicate by checking (A) or (B) below which paragraph applies:
- (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).
  - (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.
- (4) The following active ingredients in this product qualify for the formulator's exemption.

	Source	
Active Ingredient	Product Name	Registration Number
Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride		
Glutaraldehyde		
Signature	Name and Title Gary E. Gaumer	Date

EPA Form 8570-27 (Rev. 8-95)

White - EPA copy Yellow - Applicant copy



World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

November 22, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (NOTIFICATION)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Attached to this cover are the documents that have been requested by the USEPA, in Ms. Velma Noble's November 10, 2010 letter. These documents support Preserve International's desire to register, via notification, two additional alternate formulas for our product Synergize, EPA registration number 66171-7.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer
President

Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511



Subject:

Synergize

EPA Registration No.: 66171-7 Decisions 441288 and 441289

Notifications Dated: September 30, 2010 EPA Receipt Dates: October 12, 2010

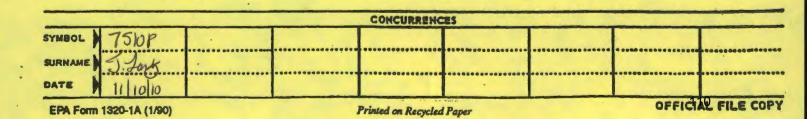
Dear Mr. Gaumer,

This letter acknowledges receipt of the notifications identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRRA), as amended and PR Notice 98-10.

Notification to add Alternate Formulations

Based on a review of the submitted information these notifications are unacceptable due to the concerns listed below.

- 1) You have submitted two alternate formulations dated 9/24/10. Neither formulation has an identifier. These two formulas must be identified to indicate that each is a distinctly different formula. It is suggested that you name each in a manner such as the following: #1 and #2 or A and B, etc.
- 2) You have requested an alternate source of the active ingredient Glutaraldehyde. When such a change is made by notification, you must submit a Formulator's Exemption Statement along with the application. (PR Notice 98-10, III. A) It appears that such a form was requested to support the use of this alternate active ingredient in 2003. According to our records no form was submitted in response to that request.
- 3) Your formulation containing includes an attachment listing alternate sources of Your Confidential Statement of Formula (CSF) form indicates one source: If you would like to add an additional source of Glutaraldehyde to this formula, revise the CSF to reflect your intention.



## **General Comments**

Submit revised CSFs addressing the issues noted above. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble.
Product Manager (31).
Regulatory management Branch I. Antimicrobials Division (7510P)

7510P:T.Lantz:11/10/10:66171-7 a b notification

Antimicrobial Division/Regulatory Management Branch II

A			Completed	by Product	Manag			
PRODUCT	REVIEWER:		Trach			RME	I_ TEA	AM_31
Description	on of Action:	n	Tracy lotifi	entir			File Symbol/I	_
Decision N	No. 441289	Submission	No. 884	345	Fee for Se	rvice A	ction Code:	
FQPA Acti	ion Code: 33	Non-FQPA	Action Co	de:	PRIA F	PRIA FEE AMOUNT: \$		
	Carl Start	MONTH		DAY			YEAR	
APPLICAT	ION DATE	9	30				2010	
EPA PIN D	ATE	10	12				2010	
DATE PM R	RECEIVED FROM						2010	
Date sent	to Reviewer						2010	
DATE SEN	DATE SENT TO SCIENCE						2010	
DATE REC	EIVED FROM							
PRADUE	DATE	TH.	11	2010	NEGOTI DUE DA			
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environment Fate	RAS Ecol Effect	ogical	RASSB Chronic Toxicology	RASSB Exposure Residue
COMMENT	s: Notifi	cotin - CSF revis	6, re	to TIA	5			
ATTACHMI	ENTS: -LABE	LING	J-CSF(S)	□-DAT		□-ОТН	ERS	h e
DATE EEE	PAID:		RESPON	NSE CODE:		PESPO	NSE DATE:	



World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

September 30, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International hereby submits this notification for minor formulation change for Synergize, EPA registration number 66171-7.

To support the notification of minor formulation change, please find a revised confidential statement of formula.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer President

"The Solution Is Preserve"

Please read instructions on reverse before completing form.

Form Approved, CMB No. 2070-0060,



**United States** 

	Registration
~	Amendmen
	Other

**OPP Identifier Number** 

<b>SEPA</b>	Environmenta Washi	ngton, DC 20			✓ Amenda Other	ment	
		Application	on for Pestici	de - Sec	tion I		
1. Company/Product Number	r 66171-7			Product Mar		3. Pr	oposed Classification
4. Company/Product (Name)	ynergize		PM# 31				
5. Name and Address of App Preserve International PO Box 17003 Reno, NV 89511	plicant (Include ZIP Co	de)	(b)(i), r to: EPA I	ny product		tical in co	FIFRA Section 3(c)(3) imposition and labeling
			Section -				
Notification - Explain	below.			Agency let "Me Too"	ed labels in repsons tter dated Application. plain below.	e to	
Explanation: Use addition Application for accelerated re							
1. Material This Product Wil			Section - I				
Child-Resistant Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	Water Soluble F Yes No  If "Yes" Package wgt	No. per containe		Metal Plastic Glass Paper	Specify)
3. Location of Net Contents	Information		tail Container 50g,55g,30g,15g,5	ig,4x1g	5. Location of La		ons
6. Manner in Which Label is	Affixed to Product		greph glued islad		or Sleeve		
			Section - I	V			145
1. Contact Point (Complete	items directly below	for identification	on of individual to b	e contacted	, if necessary, to pe	rocess this	application.)
Name Gary Gaumer			Title President			Telephon 775-853-9	e No. (Include Ares Code) 9776
	ments I have made on ny knowlinglly false or law.		d all attachments th				6. Date Application Received (Stamped)
2. Signature			3. Title President				
4. Typed Name Gary Gaumer			5. Date September 30, 2010				

## Antimicrobial Division/Regulatory Management Branch II

A			Completed	by Product I	Wanag				
PRODUCT	REVIEWER:		Trace			RMB	I_ TEA	AM31	
Description	on of Action:	Translotific	entri		EPA File Symbol/Reg No.				
Decision N	No. 44/288	Submission	No.884	342.	Fee for Ser	vice A	ction Code:		
FQPA Acti	ion Code: 332	Non-FQPA	Action Co	de:	PRIA FE	PRIA FEE AMOUNT: \$			
		MONTH		DAY	The state of the s		YEAR		
APPLICAT	ION DATE	9	3	O			2010		
EPA PIN D	ATE	10	12				2010		
DATE PM R FRONT ENI	RECEIVED FROM			,			2010		
Date sent	to Reviewer					-1.0	2010		
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DATE REC	EIVED FROM	To strong the						4	
PRIA DUE	DATE		VI.	2010	NEGOTIA DUE DAT	SEA STATE OF			
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Éfficacy	RASSB Environmen Fate	RASS Ecolo Effect	gical	RASSB Chronic Toxicology	RASSB Exposure Residue	
COMMENT	s: Notifi		6 re CSF	1	5				
ATTACHMI	ENTS: -LABE	LING	I-CSF(S)	□-DATA	<u> </u>	□-ОТН	ERS		
DATE FEE	PAID:		RESPO	NSE CODE:	F	RESPO	NSE DATE:		



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Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

September 30, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International hereby submits this notification for minor formulation change for Synergize, EPA registration number 66171-7.

To support the notification of minor formulation change, please find a revised confidential statement of formula.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer President

1111120

Please read instructions	on reverse before completing t	in em	Form A	nroved	OMB No. 20		991 700 D. Approval expires 2-28-9
<b>\$EPA</b>	United Environmental Pro	States		~	Registrati Amendme Other	on	OPP Identifier Number
	App	olication for	Pesticide - Sec	ction			
1. Company/Product Num	66171-7		2. EPA Product Ma Ms. Velma Noble	_		3. Pro	oposed Classification  None Restricted
4. Company/Product (Na	Synergize		PM# 31			] -	, none
PO Box 17003 Reno, NV 89511	Applicant (Include ZIP Code)  nal  this is a new address			is sim	ilar or identica	al in co	FIFRA Section 3(c)(3) mposition and labeling
		Sec	tion - II				
Notification - Exp	esponse to Agency letter date	or section I and S	Agency le "Me Too" Other - Ex	tter dat Applic	ation.	0	
		Sec	tion - III				
1. Meterial This Product				_			
Child-Resistant Packagin Yes No Certification must	Yes No If "Yes" No	o. per If "Ye			V	Metal Plastic Glass Paper	
be submitted	Unit Packaging wgt. co	ntainer Packa	ge wgt contain	91		Other (S	ipecify)
3. Location of Net Conte	Container 4. S	ize(s) Retail Conta 275g,250g,55g,	iner 30g,15g,5g,4x1g	5. Lo	ocation of Label	Direction	ons
6. Manner in Which Lebe	I is Affixed to Product	Lithograph Paper glued Stenciled	Oth	er Sk	seve		•••••
		Sec	tion - IV				
1. Contact Point (Compl	ete items directly below for ide	entification of indiv	vidual to be contacted	l, if nec	essary, to proc	ess this	application.)
Name Gary Gaumer		Titla Preside	nt		77	elephon 75-853-9	e No. Hinclude Area Code)
-	atements I have made on this any knowlingly false or misle						6. Date Application Received (Statuped)
2. Signature		3. Title Presiden	nt				•••••
4. Typed Name Gary Gaumer		5. Date	September	30, 2	010		

Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511

Subject:

Synergize

EPA Registration No.: 66171-7

Amendment Date: September 30, 2010 EPA Receipt Date: October 12, 2010

NOV 2 2010

Dear Mr. Gaumer,

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIRRA), as amended and PR Notice 98-10.

Notification to add Alternate Brand Names:

• "Synergize Orange" and "Synergize Orange NF"

Based on a review of the submitted information this notification is acceptable. This notification will be made part of the record for this file.

### **General Comments**

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble.

Product Manager (31).

Regulatory management Branch I. Antimicrobials Division (7510P)

7510P·T Lantz:11/1/10:66171-7 notification CONCURRENCES											
SYMBOL \$ 7510P											
SURNAME ) J. Jurk		***************************************									
DATE											
EPA Form 1320-1A (1/90)	Printed on Recycled Paper	OFFICIAL FILE COPY									

## Antimicrobial Division/Regulatory Management Branch II

A	4	•	Completed	by Product I	Mana			
PRODUCT	REVIEWER:	T	ray			RMB	_I TE	AM_31
Descriptio	n of Action:	1 yoth	fi ent	ن، ا	, n		File Symbol/	
Decision N	10.441290	Submission	No. 884	346	Fee for Ser	vice A	ction Code:	
FQPA Acti	on Code: 33	Non-FQPA	Action Co	de:	PRIA FE	EAMO	OUNT: \$	
	<b>THE 3</b> F	MONTH		DAY			YEAR	E ELEVA
APPLICAT	ION DATE	9	3	0			2010	
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DATE PM R FRONT END	ECEIVED FROM						2010	
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DATE SEN	DATE SENT TO SCIENCE					2010		
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PALADUE	DATE	N. Maria		2010	NEGOTIA DUE DAT			
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmen Fate	RASS Ecolo Effect	gical	RASSB Chronic Toxicology	RASSB Exposure Residue
COMMENT	nbf.f.	entm - Hernate Bran	6 re	· for Tr	nh			
ATTACHME	ENTS: -LABEI	LING	⊒-CSF(S)	□-DATA	i (	□-ОТН	ERS	
DATE FEE	PAID:		RESPO	NSE CODE:		RESPO	NSE DATE:	



World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446 September 30, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International hereby submits this notification for Alternate Brand Name for Synergize, EPA registration number 66171-7.

Alternate Brand Name requested: Synergize Orange Alternate Brand Name requested: Synergize Orange NF

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer President

	on reverse before comple							OPP Identifier Number	
<b>\$EPA</b>	Environmenta	United States  I Protection  ington, DC 206			~	Registra Amend Other		OPP Identifier Number	
		Application	on for Pestic	ide - Sec	ction	I			
1. Company/Product Nu	Imber			Product Ma			3. Pr	roposed Classification	
	66171-7		Ms. Ve	elma Noble	9			None Restricte	
4. Company/Product (N	Synergize		PM# 31						
5. Name and Address of Preserve Internation PO Box 17003 Reno, NV 89511	f Applicant <i>(Include ZIP C</i> i Onal	ode)	(b)(i), i to:	my product	is sim	ilar or iden	tical in co	FIFRA Section 3(c)(3) omposition and labeling	
Check it	f this is a new address		Produ	uct Name					
			Section -						
Explanation: Use ad Notification for Alternate Synergize Orange Synergize Orange NF  1. Material This Produc Child-Resistant Packagi	response to Agency lette plain below.  ditional page(s) if necessa Brand Names:  t Will Be Packaged In:  ng Unit Packaging		Section -	Agency le "Me Too"  Other - Ex	tter dar Applic	ation.	Containe		
Yes No	Yes No	No. 1100	Yes No	No			Metal Plastic Glass Paper	e :	
<ul> <li>Certification mus be submitted</li> </ul>	If "Yes" Unit Packaging wgt	No. per container	If "Yes" Package wgt	No. per contain			_	Specify)	
3. Location of Net Cont	ents Information		teil Container 50g,55g,30g,15g,	5g,4x1g		ocation of La		ons	
	el is Affixed to Product	Lithog	graph glued siled	Oth	er Sk	eve			
			Section - I	V					
1. Contact Point (Comp	plete items directly below	for identification	on of individual to L	e contected	i, if nec	essary, to p	rocess this	application.)	
Name Gary Gaumer			Title President				<b>Telephor</b> 775-853-	ne No. (Include Area Code) 9776	
•	stetements I have made or at any knowlinglly false or able law.		all attachments th					6. Date Application Received (Stamped)	
2. Signatura			3. Title President						
4. Typed Name Gary Gaumer			5. Date	otember	20 2	010			

# Material to be added to an e-Jacket/Jacket

	Reg. No
1. 🗆	Placement within the e-Jacket/jacket:
	□ Default: (chronological, top/newest)
	□ Description: (PDF page number, i.e., "before page 45")
2. [	Send to Data Extraction contractors this material:   Newly stamped accepted label
calura	□ Notification
X Kinch	□ New CSF
60	Other:
must Then Inform	ach this coversheet to the top of the material or jacket. It be well organized and clipped together, NOT STAPLED. give the material with this coversheet to staff in the nation Services Center (Room S-4900).
Revi	ewer's Name:
Pho	ne: 703 308 6415 Division: AD
Date	: 11 10 10

Created January 26, 2009





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 23

Mr. Gary E. Gaumer President Preserve International P.O. Box 17003 Reno, NV 89511

Subject:

Synergize

EPA Registration No.: 66171-7 Application Date: April 23, 2010 EPA Receipt Date: April 26, 2010

Dear Mr. Gary E. Gaumer

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable with the conditions listed below.

## **Proposed Amendment**

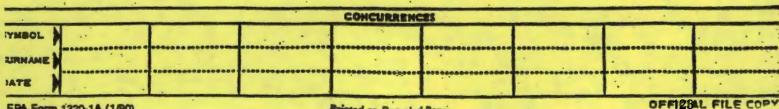
Revise label per Agency letter dated March 30, 2010

### **Conditions**

Revise the label as follows:

On page two of the label revise the heading "Sanitizing Hatchery Rooms, Incubators and Hatcheries, Poultry Houses and Livestock Buildings By Fogging" by deleting the word Sanitizing

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.



Should you have any questions or comments concerning this letter, please contact Velma Noble at 703-308-6233

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosures: Stamped Label

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed,

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Bams, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute o precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray aking sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gal-Ion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Lsave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes. 7) Immerse equipment used in handling and restraining animals, forks, shovels, and
- scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock tment has been absorbed, set, or dried.
- phly scrub treated feed racks, troughs, automatic feeders, fountains, waterers coment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking safers, bentik houses.
  2) Remove all animals and feed from the oremises, vehicles, and enclosures.
  3) Remove all gross soil, bedding, marrier, caked as disception webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or delegent and linse with water.
- 6) Thoroughly saturate all surfaces with a Solution of 1/2 of SYNERGIZE per gallon of water (1:256), using conventional spraying setteds. Allow to remain in contact with this solution for at least 10 minutes •



# SYNERGIZE

## CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....26.00% Glutaraldehyde. ...7.00% Inert Ingredients:... .67.00% TOTAL \_100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

#### See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:258) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No. EPA Est. Patent Number:

66171-7 66171-TN-001, 66171-CA-001 5,891,922

Batch No:

**Net Contents:** 

with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide,

rungicide, and Rodenticide Act as umended, for the pesticide, registered under EPA Reg. No. 66171-7

Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com Page 1 of 2

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for quidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promotiv after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two

General: Consult Federal, State or local disposal authorities for approved aiternative procedures

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN. Corrosive, Causes Irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated dothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### FIRST AID

IF IN EYES: Hold eye open and rinse 'owly and gently with water for 15-20 minutes; remove contact lenses, if present, after t e first 5 minutes, then continue rinsing eye; call a poison control center or doctor for trea ment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; s : Il a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air. It person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person slo a class of water if able to swallow; do not include vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to agunconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavaga. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

Sanitizing Hatchery Rooms. Incubators and Hatchers, Poultry Houses and Livestock Buildings By Fogging:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

#### A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

#### **B) INCUBATORS AND HATCHERS:**

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breather this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

#### **WILTRY HOUSES AND LIVESTOCK BUILDINGS:**

he house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, liveslock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog should have settled and the house can now be opened and alred. The house should be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they should be washed with detergent and water before use for poultry or livestock.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Exercicia Coli F18
Fine circovirus Type 2



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## DOT SHIPPING NAME

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III



World Headquarters 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728 • USA: (800) 995-1607

Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446

April 20, 2010

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

The attached label addresses all issues raised in your March 30, 2010 letter. For your reference, we have highlighted one copy reflecting the required changes.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

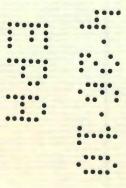
Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President



Gary E. Gaumer Preserve International P.O. Box 17003 Reno, NV 89511



Subject:

Synergize

EPA Registration No.: 66171-7

Amendment Date: December 16, 2009 EPA Receipt Date: December 30, 2009

Dear Mr. Gaumer,

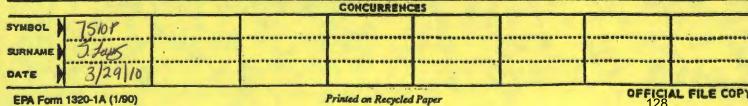
The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable due to the concerns listed below:

- Revise directions for fogging
- Adding directions to sanitize egg shells

## **Deficiencies**

The cited label for 71355-1 was approved in 2005 prior to the ADBAC RED and thus is not in agreement with the RED. Your last stamped label included this use for fogging in animal premise. The comments in the letter accompanying your stamped label dated 6/24/09 were intended to bring your label into agreement with the label comments in the RED for fogging. The proposed revised fogging directions are not in agreement with our comments of 6/24/09 nor are they in agreement with the RED. The following revisions as per the RED have not been addressed:

- When sanitizing incubators and hatchers label must include the following text: Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs.
- When sanitizing hatchery rooms label must include the following text: Remove all animals and feed from premise, vehicles and enclosures.



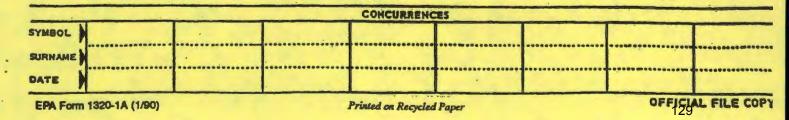
- Fogging applications must include a 2 hour Reentry Interval
- Your label must indicate that a dust mist respirator must be worn when diluting the product into the fogging equipment.
- In addition, as per your last stamped label, include language to indicate that fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting on room surfaces. Fogging is not used as a sanitizing treatment.

## **Other Concerns**

Your label indentifies a website. Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

In addition, revise the label to include the follows changes:

- 1) Your product is not cleared as a food contact sanitizer. You have proposed that this product be used to sanitize eggs shells intended for food. In your reply to this letter, indicate the study, by MRID that is being used to support this claim. Please also be aware that all ingredients, active and inert in your formula must be cleared for use in food as per 40 CFR 180.940. As such all of the inert ingredients in your formulation must be cleared for use in food. If any inert does not have a tolerance or tolerance exemption under 408 and the product includes a food use on the label, then that inert is not approved for use in the product. If the inert is on the FDA GRAS list we would still not approve it for use on food unless there is a tolerance or tolerance exemption under 408. Should you decide to pursue this use, submit a revised Basic CSF for review. Indicate the specific 40 CFR or FIFRA 408/409 references for each of the ingredients in your formulation.
- 2) Propose revised Container Handling directions which are in agreement with a product such as yours with claims for public health pests. The container rinsate should not be emptied into the application equipment as this would produce an unknown dilution that would not be efficacious. The rinsate should be disposed of as pesticide waste.



### **General Comments**

Please include a copy of this letter with your revised amendment. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

7510P:T.Lantz:3/29/2010:66171-7j

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes, This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### **USE DIRECTIONS:**

To disirrfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:258) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of bams, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain In contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried,
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS. RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider wabs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



# SYNERGIZE

## CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

#### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride26	.00%
Glutaraldshyde7	.00%
Inert ingredients:	.00%
TOTAL100	.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry
- or Ilvestock or employ equipment until treatment has been absorbed, set or dried. 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers
- and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:258) for a
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### SANITIZING EGG SHELLS INTENDED FOR FOOD DIRECTIONS:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of ¼ ounce of this product per 5 gallons of warm water (or equivalent use dilution) (200 ppm active). The solution must be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product must be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot he sanitized

EPA Reg. No. EPA Est.	66171-TN-001, 66171-CA-001
Patent Number:	5,891,922
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Batch No: Net Contents:

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous, Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for quidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water, Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivelent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsete for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

#### DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled, Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shiald. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause alleroic reaction in some individuals. Wash hands before eating, drinking, chewing gurn, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 ml remove contact lenses, if present, after the first 5 minutes, then continue rinsing ev a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

## - W.

## SYNERGIZE

#### SANITIZING HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING

A) HATCHERY ROOMS: Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants.

B) INCUBATORS AND HATCHERS: Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.

It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C) POULTRY HOUSES AND LIVESTOCK BUILDINGS: After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four (24) hours. After twenty-four (24) hours before it is repopulated with poultry or livestock.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they should be washed with detereent and water before use for poultry or livestock.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2



Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

## **DOT SHIPPING NAME**

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUN 2 4 2009

Mr. Gary E. Gaumer Preserve International P. O. Box 17003 Reno, NV 89511

Subject:

SYNERGIZE

**EPA Registration Number 66171-7** Application Dated March 20, 2009 Received Date March 30, 2009

Dear Mr. Gaumer:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable the conditions listed below.

## **Proposed Amendment:**

Add hatching egg sanitizer directions

### **Conditions**

Revise your label as follows:

- 1. Revise the "Boot/Shoe Wash" directions by deleting the phrase, "tracking harmful organisms," and stating "to prevent cross contamination..."
- 2. Revise the first statement under "Environmental Hazards" to be in agreement with the ADBAC RED by stating "This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp."
- 3. Delete the "Sanitizing Using a Thermal Fogger" heading and state "Directions for Fogging Animal Premises."
- 4. Any ADBAC product supporting fogging directions for animal housing facilities and hatchery rooms must be revised to comply with the mitigation measures addressed in the ADBAC RED. You must add the statement, "wear a dust mist

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. \	DATE						·			
J	SURNAME		·	4						
	SYMBOL	app	aratus."	Also,	revise the s	econd state	ment under	Note" to rea	d :	
							gouring it			

"Under no circumstances ....within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility."

5. "Hatching Egg Sanitizer" directions are under the Food and Drug Administration's jurisdiction. If you would like to support these directions on your label, you must contact FDA and receive clearance from them. Once FDA clears your product for use as a hatching egg sanitizer, you must include a copy of FDA' letter with your resubmission.

### **General Comments:**

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Cacque Z

√eima Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: stamped label

	CONCURRENCES							
	SYMBOL							
	SURHAME							
1	DATE					•••••		
	EPA Form	1320-1A (1/90)			Printed on Recycled		OFFICI	AL FILE COPY

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% senim

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator ors, telephone booths, and garbage cans in non-animal areas associated with the noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent the ships the into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gation of water. Apply using a high pressure or coarse spray systern. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes. 7) Immerse equipment used in handling and restraining animals, forks, shovels, and
- scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain votact for at least 10 minutes.

intilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalts, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods, Allow to remain in contact with this solution for at least 10 minutes.



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## SYNERGIZE

## CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauting Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine 1000 (Outrich, Rational Country) Emu and Rhea Facility this and Common and San Vehicles.

Active ingredients: Active Ingredients: in EPA Letter Dotect.

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzy zmmonium chloride.....26.00% Glutaraidehyde.. Inert Ingredients:

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS See First Aid statement and additional precautions on side panel

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning, if burned, stay out of smoke,

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a neriod of 10 minutes
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems rithout previously notifying the local sewage treatment plant authority. For guidance con tact your State Water Board or Regional Office of the EPA.

#### SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

'NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

#### **DIRECTIONS FOR HATCHERY ROOM FOGGING:**

Prior to togging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable

\*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pents.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes inversible eye damage and skin burns. May be fatal if inhaled, Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering resolrator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gioves. Prolonged or frequent repeated skin contact may cause alleroic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using this toilet. Remove contaminated clothing and wash before reuse

#### **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mountio-moun, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may

## **DOT SHIPPING NAME**

Corrosive Liquid, Acidic, inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III

EPA Reg. No. EPA Est.		
Patent Number:		
Batch No:		- 1

Net Contents:

66171-TN-001, 66171-CA-001



Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2

#### HATOMING EGG GANTINZER:

# RISK ASSIGNMED FORM Jacket not available Antimicrobial Division/Regulatory Management Branch II

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

January 4, 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

GARY GAUMER
PRESERVE INTERNATIONAL
PO Box 17003
RENO, NV 89511-

PRODUCT NAME: SYNERGIZE

COMPANY NAME: PRESERVE INTERNATIONAL

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 66171-7 EPA RECEIPT DATE: 12/30/09

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

P. K. Alooke

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



This package includes the following	for Division		
<ul><li>New Registration</li><li>Amendment</li></ul>	AD     BPPD     RD		
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 31		
Receipt No. S-	864883		
EPA File Symbol/Reg. No.	66171-7		
Pin-Punch Date:	12/30/2009		
This item is NOT subject t	to FFS action.		
Action Code:  Requested:  Granted:  Amount Due: \$	Parent/Child Decisions:		
Inert Cleared for Intended Use	Uncleared Inert in Product		
Reviewer: Team 1	Date:1-4-10		
Remarks:			

## 7 2005

Ms. Olivia Laird Agent for Virocid Laird's Regulatory Consultant, Inc. 7804 Braemar Place Leesburg, VA 20175

Subject:

1

Virocid

EPA Registration No. 71355-1

Amendment Date: November 18, 2004 EPA Receipt Date: November 19, 2004

Dear Ms. Olivia Laird,

The following amendment submitted in connection with registration under FIFRA 3(c)(7)(A) is acceptable with the conditions listed below.

Addition of microorganisms

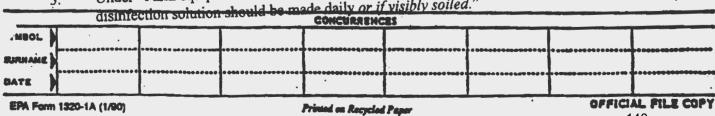
### Conditions

Revise the label as follows:

Based on the Agency letter dated February 2, 2004, the following organisms were 1. unacceptable and must be deleted from the label:

Campylobacter jejuni, Cornebacterium pseudotuberculosis, Klebsiella pneumoniae, Listeria monocytogenes, Orithobacterium rhinotracheale, Pateurella multocida, Salmonella choleraesuis serotype enteritidis, Haemophilus paragallinarum, Mycoplasma synoviae, Mycoplasma gallispecticum,, Bordetella avium, Salmonella cholerasuis serotype pulorum, Fusarium dimerum, and Pencillium expansum.

- You must add a double asterisk, \*\*, to the bacteria, Mycoplasma hyponeumoniae, since the product is effective in the presence of 25% soil load and 400 ppm AOAC synthetic 2. water.
- Under "Farm equipment and animal housing building," revise step F by stating, "Fresh 3. disinfection solution should be made daily or if visibly soiled."



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3. Under "Storage and Disposal" instructions, bold the subheadings, Storage, Pesticide Disposal, and Container Disposal."

### **Data Summary**

Data Requirement	Means of Support	Status
Virucidal Effectiveness Against Newcastle Disease Virus	Submitted study, MRID 464106-01	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min.
Virucidal Effectiveness Against Marek's Disease Virus	Submitted study, MRID 4641606-02	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min
AOAC Use Dilution Test Against Mycoplasma Hyopneumoniae	Submitted study, MRID 464106-03	Acceptable at 1:400 dil in 25% soil, 400 ppm water at 10 min
Virucidal Effectiveness Against Avian Infectious larynotracheitis virus	Submitted study, MRID 464106-04	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min
Virucidal Effectiveness Against Porcine Respiratory and Reporductive Syndrome Virus	Submitted study, MRID 464106-05	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min
Virucidal Effectiveness Against Avian Infuenza Virus	Submitted study, MRID 464426-01	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min
Virucidal Effectiveness Against Avian Reovirus	Submitted study, MRID 464106-07	Acceptable: Not Reviewed
Virucidal Effectiveness Against Pseudorabies Virus	Submitted study, MRID 464106-08	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min
AOAC Use Dilution Test S. suis, E. coli, S. choleraesuis, ssp. choleraesuis, serotype typhisuis	Submitted study, MRID 464106-09	Acceptable at 1:400 dil in 5% soil, 400 ppm water at 10 min

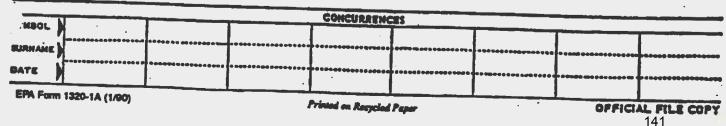
Please Note: The Agency reviews animal disease data if they have been designated by the World Organization for Animal Health as diseases that causes significant economic impact. The submitted study, MRID 464106-07, was not reviewed because Avian Reovirus is not recognized as a disease that causes significant economic impact.

### **General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite\_all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling.



If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble

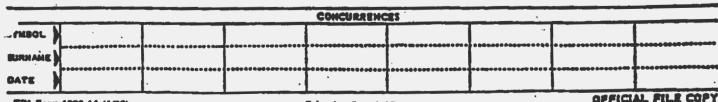
Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Efficacy Data Evaluation Enclosure:

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Stamped Label



# C VIROCID 3°

## CONCENTRATED BROAD SPECTRUM DISINFEÇTANT

Active ingredients:

ALKYL\* DIMETHYL BENZYL AMMONIUM CHLORIDE \*(50% C14;40% C12;10% C16) 17.060 % (by wt) DIDECYL DIMETHYL AMMONIUM CHLORIDE 7,800 % • 10.725 % .... **GLUTARALDEHYDE** 64.415 % ...

Inert ingredients

100.000 %

## KEEP OUT OF REACH OF CHILDREN **DANGER**

VIROCID is eff

BACTERIA	Dilution
Selmonella Choleraesuis (ATCC 10708)*	1:400
Staphylococcus aureus (ATCC 6538)*	1:400
Pseudomonas aeruginosa (ATCC 15442)*	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
	1:400
<b>J</b> *	1:400
	1:400
	1:400
Mycopiasma hyopneumoniae (ATCC 25934)*	1:400
Streptococcus suis (ATCC 43765)*	1:400
Salmonella cholerasuis subsp. Cholerasuis, serotype typhisuis (ATCC 8321)*	1:400
scherichia coli (ATCC 11220)	1:400
	1:256
<u> </u>	1:256
FUNGUS (on equipormental surfaces)	
	1:400
	1:400
ricophyton mentagrophytes (ATCC 9533)	1:400
VIRUS (on environmental surfaces)	
Porcine circovirus, type II (PCV, PT-1 cell)*	1:200
Pseudorabies (American BioResearch Laboratories)*	1:400
Porcine Respiratory and Reproductive Syndrome (Arko Laboratories)*	1:400
Ivian Reovirus (Spafas Strain)*	1:256
farek's Disease (Spafes Strain)*	1:400
lewcastle Disease (Spafas Strain)*	1:400
lvien Influenza (Turkey/Wis/66 strein – H9N2)*	1:400
Avian Infectious Laryngotrachettis (Charles River laboratories)*	1:400
nfectious Bursal Disease of Chickens (SPAFAS Strain 2512)*	1:400
Algae and slime forming bacteria in recirculating water	25-50
cooling systems and evaporative condensers	

\*in the presence of 400 ppm AOAC synthetic hard water and 5% soil load



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	FIRST AID STATEMENTS			
Have product cont	ainer with you when calling the poison control center, doctor, or going for medical treatment.			
IF IN EYES	<ul> <li>Hold eyelids open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> </ul>			
	Call a poison control center or doctor for treatment advice.			
IF ON SKIN OR CLOTHING	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul>			
	Call a poison control center or doctor for treatment advice.			
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> </ul>			
	Do not give anything by mouth to an unconscious person.			
IF INHALED	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth- to- mouth, if possible.</li> </ul>			
	Call a poison control center or doctor for further treatment advice.			
	NOTE TO PHYSICIAN:			
	Probable mucosal damage may contraindicate the use of gastric lavage.			

### **APPLICATION:**

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Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment :

- 1. Farm Equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings)
- 2. Hatchers, Setters, and chick processing facilities
- 3. Food processing plants (slaughterhouses)
- 4. Trucks and other vehicles
- 5. Veterinary hospitals.

Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging. Control of algae and slime forming bacteria in recirculating water cooling systems and evaporative condensers.

### **DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

### Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment:

1. Farm equipment and animal housing buildings (poultry & turkey grow-out houses, laying houses, swine production and housing, barns and large animal buildings):

For disinfection of hard, non-porous surfaces: stainless, galvanized and painted steel, copper, aluminum, finished wood, vinyl, plastics, glazed tiles, sealed brick walls, aluminium sandwich panels and feeding/drinking equipment:

- A. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
- B. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the appropriate disinfection solution by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes.
- C. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed or dried.

see table top of label to determine the appropriate disinfection solution

- D. Thoroughly scrub treated feed racks, troughs, and other feeding and water appliances with soap or detergent and rinse with potable water before reuse.
- E. Disinfection of equipment: Immerse all halters, ropes, and other types of restraining equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution\* for 10 minutes. Allow to air dry.
- F. Fresh disinfection solution should be made daily.

# 2. Hatcheries :

Remove all animals from the area. Thoroughly clean all surfaces (hatchers, setters, trays, racks, carts, sexing tables, chick boxes, cages) with soap or detergent, then rinse with water. Saturate all surfaces with the appropriate disinfection solution\* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Do not house animals or employ equipment until surfaces have been absorbed or dried. Fresh disinfection solution should be made daily or if visibly soiled.

3. Food processing plants (including Chicken Processing Facilities):

Before using this product, all food products and packaging materials must be removed from the room or carefully protected. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Disinfect hard, non-porous surfaces by applying the appropriate disinfection solution\* with a coarse spray, mop, or sponge. All surfaces must remain thoroughly wet for 10 minutes. Allow to air dry. A potable water rinse is required for all surfaces that come into contact with food.

# 4. Trucks and other vehicles :

Clean all vehicles including mats, crates, cabs, and wheels with high pressure water. Use the appropriate disinfection solution\* to treat all vehicles. Leave all treated surfaces exposed to disinfectant solution wet for 10 minutes. Allow to air dry.

5. Veterinary hospitals:

For disinfection of the following hard non-porous surfaces: floors, walls, ceilings, counters, cages, feeding/drinking equipment, and handling/restraining equipment. Remove animals and feed from the premises. Thoroughly clean all surfaces with soap or detergent, then rinse with water. Saturate surfaces with the appropriate disinfection solution\* by using a coarse spray, mop, or sponge. Surfaces must remain wet for 10 minutes. Immerse all leashes, muzzles, ropes or other types of equipment used to restrain or handle animals as well as shovels, scrapers, and forks used to remove manure and litter. Do not house livestock or employ equipment until surfaces have been absorbed or dried. Thoroughly scrub treated feeding and watering equipment with soap or detergent and rinse with potable water before reuse. Fresh disinfection solution should be made daily or if visibly soiled.

Preparation table:

dilution	Preparation method
1:1000	
1:400	1/3 fluid ounce per gallon of water
1:256	1/2 fluid ounce per gallon of water
1:200	3/4 fluid ounce per gallon of water

APR 7 2005

71355-1

# Sanitizing hatchery rooms, incubators and hatchers, poultry houses and livestock buildings by fogging

A. Hatchery rooms

Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals

entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants.

B. Incubators and hatchers:

Prepare a stock solution of one (1) part VIROCID to four (4) parts water. Fog 3 ounces for 100 cubic feet of this into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog.

It is also satisfactory to fog setters and hatchers with a 1:1000 solution of VIROCID. If this is done, fog

for 30-90 seconds once per hour or once every two hours.

C. Poultry houses and livestock buildings :

After the house has been depopulated and cleaned as in 1. A to F under "Disinfection of non-food surfaces, farm, animal, and poultry housing facilities and equipment", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as tight as possible. Prepare a stock solution of one (1) part VIROCID to four (4) parts water (25 fluid ounce VIROCID to 100 fluid ounce water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yard. The fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four hours. After twenty-four hours, the fog should have settled and the house can now be opened and aired. The house should be opened for a minimum of twenty-four hours before it is repopulated with poultry or livestock.

Note: The generated fog is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after the actual fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt, sleeves and pants. If feeders and waterers were not removed from the premise during treatment, or were not adequately covered to prevent contact with treatment, they should be washed

with detergent and water before use for poultry or livestock.

# Control of sigae and slime forming bacteria in recirculating water cooling systems and evaporative condensers

A. VIROCID should be added in the system directly and not mixed with any other chemicals or additives; it should be added at a point where uniform mixing and even distribution will occur.

B. Severely fouled systems should be chemically and/or manually cleaned before adding VIROCID treatment. If

Algae/slime growth is absent or minimal, proceed with the initial dose.

C. Initial Dose 2.5 fluid ounces of VIROCID per 100 gallons of water (50ppm) in the system. Repeat treatment until algae/slime growth is controlled. Maintenance Dose: After algae control is evident/achieved, apply 1.25 fluid ounces of VIROCID per 100 gallons of water (25ppm) in the system every 7 days (weekly). Repeat treatment as needed to maintain algae/slime control.

ACCEPTED
with GOMMENTS
in EFM Letter Dated:

APR 7 2005

Under the Pederal Schooleide, Pungicul Jose Colomocale Aci as emensish tortal a patched, regulated under IATA bog. No.

71355-

# STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal

Storage: Store in a cool, dry place in tightly closed container away from children. Avoid temperatures below 23°F and above 113°F.

Disposal of pesticide: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representatives at the nearest EPA Regional Office for guidance.

Disposal of container: Triple rinse. Then offer for recycling or puncture and dispose in a sanitary landfill. Disposal by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

# **ENVIRONMENTAL HAZARDS:**

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

# PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear, protective clothing, and rubber gloves. Harmful if inhaled. Avoid breathing vapor. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

# LIMITED WARRANTY AND DISCLAIMER:

The manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is a reasonable fit for the purposes set forth in the directions for use when it is used in accordance with such directions; and (c) that the directions, warnings and other statements on this label are based upon responsible expert's evaluation of reasonable tests of effectiveness and of toxicity to laboratory animals. Tests have not been made on all varieties or in all states or under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make, any other warranties, expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the buyer shall be solely responsible for, any and all loss or damage which results from the use of this product in any manner which is inconsistent with the label directions, warnings or cautions. Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability is based in the contract, negligence, strict liability in tort of otherwise, shall be limited, at the manufacturer's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect or consequential damages resulting from the use or handling of this product.

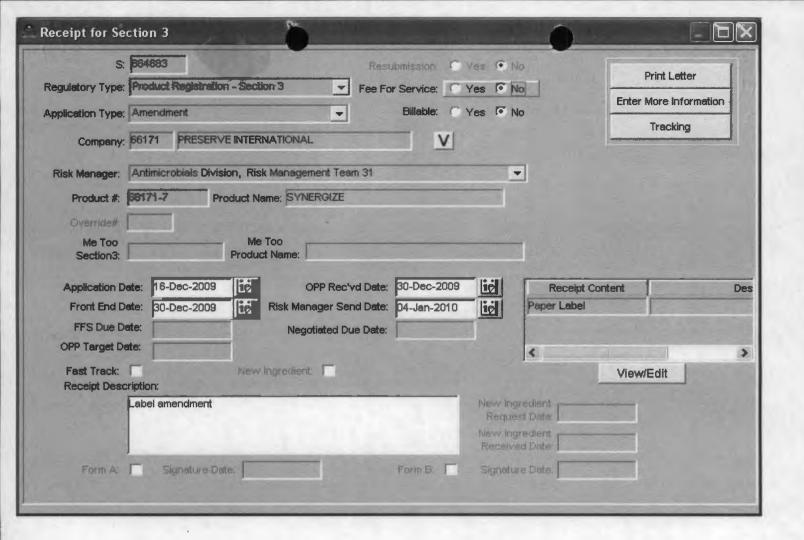
EPA Reg. N°: 71355-1 EPA Est. N°: 71355-BEL-001 BATCH N°: see top / bottom EXPIRY DATE: see top / bottom

Net contents : see top / bottom

# Produced by:

CID LINES NV/SA - Waterpoortstraat 2 - B 8900 IEPER - BELGIUM - EUROPE Phone: 011-32-57-217877 - Fax: 011-32-57-217879 http://www.cidlines.com - info@cidlines.com







Office of Gary E. Gaumer P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 853-9212 • email: gegaumer@preserveinc.com

December 16, 2009

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

# **Proposed Amendments:**

Sanitizing Hatchery Rooms. Incubators and Hatchers, Poultry Houses and Livestock Buildings By Fogging

We have included and highlighted a product, Virocid EPA Registration number 71355-1, with similar ingredients and similar fogging directions. In addition, we have highlighted a Synergize label with the proposed changes.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President



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# States

FUITH ADDITOVED	1. UMB NO. 40/0-0000
	Restration
×	Amendment
	Other

OPP Identifier Number

Environmental Protection Washington, DC 2046	•	× Amendmen Other	nt
Application	n for Pesticide - Sec	tion I	
1. Company/Product Number 66171-7	2. EPA Product Man 31	ager	3. Proposed Classification
4, Company/Product (Name) SYNERGIZE	PM#		None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Preserve International PO Box 17003 Reno, NV 89511  Check if this is a new address	(b)(i), my product i to: EPA Reg. No. 7	is similar or identical i	with FIFRA Section 3(c)(3) in composition and labeling
	Section - II	VIIOCIU	
Amendment - Explain below.      Resubmission in response to Agency letter dated      Notification - Explain below.  Explanation: Use additional page(s) if necessary. (For section Revision of fodding directions.	Final printed Agency lett "Me Too" /  Other - Exp	Application.	
	Section - III		
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging  Yes* No No No No No No. per Unit Packaging wgt. container	Water Soluble Peckaging  Yes No  If "Yes" Package wgt No. per containe	Gla Par	
3. Location of Net Contents Information 4. Size(s) Return Label Container	ail Container	5. Location of Label Di On Label On Labeling e	rections
6. Manner in Which Label is Affixed to Product Lithogr Paper (Stencil	reph Othe glued led	r	
	Section - IV		
1. Contact Point (Complete items directly below for identification	n of individual to be contacted,	if necessary, to process	s this application.)
	Title President		phone No. (Include Area Code) 5-853-9476
Certificat I certify that the statements I have made on this form and I acknowledge that any knowingly false or misleading state both under applicable law.	all attachments thereto are true	o, accurate and complet ne or imprisonment or	6 Dete Application Redelived (Stamped)
a, las	President  5. Date		
Gary E. Gaumer	December 16, 2009		••••

# Material to be added to an e-Jacket/Jacket

Reg. No. 66/717
1.   Placement within the e-Jacket/jacket:
☐ Default: (chronological, top/newest)
☐ Description: (PDF page number, i.e., "before page 45")
2.   Send to Data Extraction contractors this material:
□ Newly stamped accepted label
Notification
□ New CSF
Other:
3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).
Reviewer's Name: Vel Ma Koble_
Phone: (103) 308-6233 Division: #D
Date:

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Mr. Gary Gaumer Preserve International PO Box 17003 Reno, NV 89511 DEC 10 2009

Subject:

Synergize

EPA Registration No.: 66171-7

Notification Date: October 27, 2009 EPA Receipt Date: November 10, 2009

Dear Ms. Gaumer,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c)9 and PR Notice 98-10.

# **Proposed Notification**

Update Container Disposal Statements per PR Notice 2007-4

# **General Comments**

Based on a review of the submitted information, your notification to revise the container disposal statements per PR Notice 2007-4 is acceptable and apart of the records on file.

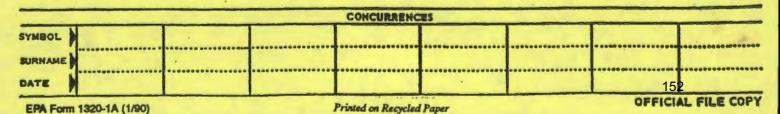
Should you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

Sincerely.

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P0



Registration

FUITT ADDITIVED, UNID NO. 2070-0000

**OPP Identifier Number** 

Washington, DC 204		× Other	ent	
Application	n for Pesticide - Sec	tion I		
1. Company/Product Number 66171-7	2. EPA Product Man	ager	3. Pro	posed Classification
4. Company/Product (Name) Synergize	PM# 031		1	None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Preserve International PO Box 17003 Reno, NV 89511	(b)(i), my product to:	is similar or identic	al in cor	FIFRA Section 3(c)(3) nposition and labeling
Check if this is a new address	Product Name			
	Section - II			
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Agency lett	d labels in response ter dated Application.	.0	
Explanation: Use edditional page(s) if necessary. (For section Notification to comply with PR Notice 2007-4. (Contain				
	Section - III			
1. Material This Product Will Be Packaged In:				
Child-Resistant Peckaging  Yes* No  Certification must be submitted  Unit Packaging  Yes No  No  H "Yes" Unit Packaging wgt.	Water Soluble Packaging Yes No If "Yes" No. per Package wgt containe	2. Type of C	ontainer Metal Plastic Glass Paper Other (S	pecify)
3. Location of Net Contents Information 4. Size(s) Re	tail Container	5. Location of Label	Direction	ns
Label Container		On Labelin	g accom	panying product
6. Manner in Which Label is Affixed to Product Lithog Paper	graph Othe	or		
	Section - IV			
1. Contact Point (Complete items directly below for identification	on of individual to be contacted,	if necessary, to proc	ess this	application.)
Name Gary Gaumer	Title President		elephon 775-853	No. (Include Area Code) 3-9776
Certificate I certify that the statements I have made on this form and I acknowledge that any knowingly false or misleading state both under applicable law.	i all attachments thereto are tru			8. Date Application Received (Stamped)
2. Signature	3. Title  President	•		•••••
4. Typed Name	5. Date	••••	•	•
Gary Gaumer	October 27, 2009	••••		



Office of Gary E. Gaumer P.O. Box 17003, Reno, NV 89511 · Bus: (775) 853-9776 · Fax: (775) 853-9212 · email: gegaumer@preserveinc.com

October 27, 2009

Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (NOTIFICATION)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE:Notification per PR Notice 2007-4, For Synergize, EPA Registration Number 66171-7

To Whom it May Concern:

Preserve International hereby submits this notification per PR Notice 2007-4.

These directions have been submitted to, and approved by Nancy Fitz, EPA OPP. Please see attached copy of the email.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

### **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed,

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the ed above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute recleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

# DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of bams, pens, stalls, chutes, and other facilities occupied or traversed by hogs or
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain tact for at least 10 minutes.

ilate buildings, and other closed spaces. Do not house swine or other livestock eatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS. RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional soraving methods. Allow to remain in contact with this solution for at least 10 minutes.



# SYNERGIZE

# CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....26.00% ..T.00% ....67.00% Inert Ingredients:..... TOTAL... .100.00%

# KEEP OUT OF REACH OF CHILDREN DANGER

## SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry
- or livestock or employ equipment until treatment has been absorbed, set or dried. 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers
- and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### **DIRECTIONS FOR USE IN POULTRY HOUSE:**

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### DIRECTIONS FOR FOGGING ANIMAL QUARTERS:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the togger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The log generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, fong shirt sleeves and pants.

EPA Reg. No. FPA Est. **Patent Number:** 

66171-7 66171-TN-001, 66171-CA-001 5,891,922

Batch No: Date Reviewed: 12 Nonents: Reviewed By: Tankly

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violating of Federal law. If these wastes cannot be disposal of by use according to tabel instruction, contact your State Predicte or Environmental Control Agency or the Hazardous Waste representative author parest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container Offer for

recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or gruivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application, equipment or a mix tank. Fill the container 1/4 full with water. Replace and eligitien clasures. Tip container on its side and roll it back and forth, equiring at least one complete revolution, for 30 seconds. Stand the container on its endmentality it eack and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative

# PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause altergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

# **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treat-

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

# **DIRECTIONS FOR HATCHERY ROOM FOGGING:**

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. Wear a dust hist respirator when mixing the use solution and pouring it into the fogging apparatus. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

\*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOR GING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2

# **SANITIZING EGG SHELLS INTENDED FOR FOOD DIRECTIONS:**

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of ¼ ounce of this product per 5 gallons of warm water (or equivalent use dilution) (200 ppm active). The solution must be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product must be subjected to a potable water rinse only if y are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The ution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.



**DOT SHIPPING NAME** 

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III

# RISK ASSIGN TO FORM Antimicrobial Division/Regulatory Management Branch II

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From: Fitz.Nancy@epamail.epa.gov

Subject: Re: 2007-4

Date: October 27, 2009 6:51:25 AM PDT

To: "Gary E. Gaumer" < gegaumer@preserveinc.com>

Cc: Fuller.Demson@epamail.epa.gov, Edwards.Dennis@epamail.epa.gov, Kasai.Jeanne@epamail.epa.gov

1 Attachment, 30.1 KB

# Gary,

We have reviewed the October 13, 2009 version of your container handling instructions attached below and we have determined that they are acceptable. These container handling instructions use the exact language from the container regulations and PR Notice 2007-4 so the changes can be made by notification.

Thank you for consulting with us ahead of time to make sure that the revised instructions are acceptable - this saves time for all of us!

If you have any questions or need more information, please contact Jeanne Kasai at kasai.jeanne@epa.gov or me.

Nancy Fitz
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-7385 (phone)
(703) 308-2962 (fax)
fitz.nancy@epa.gov (e-mail)
Pesticide container & containment web site:
http://www.epa.gov/pesticides/regulating/containers.htm

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SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective distinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, poly-ethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

### **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter,

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the site and above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse yet devices a light of the surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made distribcting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceillings of bams, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.

tilate buildings, and other closed spaces. Do not house swine or other livestock latment has been absorbed, set, or dried.

a) moroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

# DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES. CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces; and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



# SYNERGIZE

# **CLEANER-DISINFECTANT**

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzył ammonium chloride26.00	%
Glutaraidohyde7.00	%
nert Ingredients:	K
TOTAL	%

# DANGER

# SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as torks, shovels and screpers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### **DIRECTIONS FOR USE IN POULTRY HOUSE:**

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## **DIRECTIONS FOR FOGGING ANIMAL QUARTERS:**

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entening the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

EPA Reg. No. EPA Est. Patent Number:

66171-7 66171-TN-001, 66171-CA-001 5,891,922

Batch No:\_\_\_\_\_

Net Contents:

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, confact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative of the Beafirst EPA Regional Office for guidance.

Container Handling: Nonremitable Container. Denote result this container of the conta

Container Handling: Nonffillable Conditions: DonoProvalor refill this containes. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water Replace and tighten closures. Tip container on its side and roll it back and forth, chauring at least one container cover onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container (1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

# PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

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ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

# **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

iF SWALLOWED: Call a poison control center or doctor immediately for treatmenadvice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to all unconsclous person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or peticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 658-73.78.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

# **DIRECTIONS FOR HATCHERY ROOM FOGGING:**

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

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FIGURE IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2

# SANITIZING EGG SHELLS INTENDED FOR FOOD DIRECTIONS:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of ¼ ounce of this product per 5 gallons of warm water (or equivalent use dilution) (200 ppm active). The solution must be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product must be subjected to a potable water rinse only if are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The ution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.



Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com Page 2 of 2

# **DOT SHIPPING NAME**

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in e manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray iking sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gal-Ion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

# **DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:**

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- late buildings, and other closed spaces. Do not house swine or other livestock atment has been absorbed, set, or dried.

oughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

# DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS. RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking pariors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (4:256), using conventional spraying methods. Allow to remain in contact with this



Page 1 of 2

# SYNERGIZE

# **CLEANER-DISINFECTANT**

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### **Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.	26.00%
Glutanaldehyde	7.009
nert Ingredients:	67.009
TOTAL	.100.00%

# KEEP OUT OF REACH OF CHILDREN DANGER

## SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

# DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### **DIRECTIONS FOR FOGGING ANIMAL QUARTERS:**

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

EPA Reg. No. EPA Est **Patent Number:** 

66171-7 66171-TN-001, 66171-CA-001 5,891,922

Batch No:

Net Contents:

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# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your state Penticiale or Environmental Control Agency or the Hazardous Weste representative of the fleatest EPA Regional Office for guidance.

Container Handling: Nonrellitude container. Denote reuseor refill this container. Offer for

recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contented to equivalently promptly after emptying. Triple rinse as follows: Empty remaining contents the application equipment or a mix tank. Fill the container 1/4 full with wa seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drlp. Repeat this procedure two more times.

General: Consult Federal. State or local disposal authorities for approved alternative

# PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

# **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a polson control center or doctor for treat-

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may

# SYNERGIZE

# **DIRECTIONS FOR HATCHERY ROOM FOGGING:**

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. Wear a dust respirator when mixing the use solution and pouring it into the fogging apparatus. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

\*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FIGURE IN THE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2

# SANITIZING EGG SHELLS INTENDED FOR FOOD DIRECTIONS:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of ¼ ounce of this product per 5 gallons of warm water (or equivalent use dilution) (200 ppm active). The solution must be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product must be subjected to a potable water rinse only if ware to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The aution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.



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# **DOT SHIPPING NAME**

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUN 2 4 2009

Mr. Gary E. Gaumer Preserve International P. O. Box 17003 Reno, NV 89511

Subject:

SYNERGIZE

EPA Registration Number 66171-7 Application Dated March 20, 2009 Received Date March 30, 2009

Dear Mr. Gaumer:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable the conditions listed below.

# Proposed Amendment:

Add hatching egg sanitizer directions

# Conditions

Revise your label as follows:

- 1. Revise the "Boot/Shoe Wash" directions by deleting the phrase, "tracking harmful organisms," and stating "to prevent cross contamination..."
- 2. Revise the first statement under "Environmental Hazards" to be in agreement with the ADBAC RED by stating "This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp."
- 3. Delete the "Sanitizing Using a Thermal Fogger" heading and state "Directions for Fogging Animal Premises."
- 4. Any ADBAC product supporting fogging directions for animal housing facilities and hatchery rooms must be revised to comply with the mitigation measures addressed in the ADBAC RED. You must add the statement, "wear a dust mist

	respira	ator when n	nixing the use	अधिकारिक व	gspouring it	into the rogg	ing	
SYMBOL	appara	tus." Also	, revise the s	econd state	ment under	Note" to rea	d:	
SURNAME								
DATE								
					*unit		DESIGN	A EU E COPY

- "Under no circumstances ....within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility."
- 5. "Hatching Egg Sanitizer" directions are under the Food and Drug Administration's jurisdiction. If you would like to support these directions on your label, you must contact FDA and receive clearance from them. Once FDA clears your product for use as a hatching egg sanitizer, you must include a copy of FDA' letter with your resubmission.

# **General Comments:**

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely, Mark

Welma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: stamped label

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas

SYNERGIZE is for use on glazed ceramic and tile surfaces, steinless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vlnyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane,

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes, This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator ors, telephone booths and garbage cans in non-animal areas associated with the noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent the contelning one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray systern. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

# DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturete all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and rapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain tact for at least 10 minutes.

ntilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking pariors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes



# SYNERGIZE CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcherles and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Ascillet National Residue (Ostrich, Emu and Rhea Facilities, Call Pens, and accordated Farm Vehicles.

Active Ingredients: EPA Letter Dated.

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzy ammonium chloride.....26.00% **Active Ingredients:** Glutaraldehyde. Inert Ingredients: KEEP OUTLE DE LE CHIOF CHILDREN LEGISTE PANGERNO. 666171-7

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal, PESTICIDE STORAGE:

Store away from heat. Do not trensfer to another container. Do not reuse empty container CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapera used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rtnse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fooger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, googles, long shirt sleaves and pants.

### DIRECTIONS FOR HATCHERY ROOM FOGGING:

SANITIZING USING A THERMAL FOGGER:

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one guart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and pouttry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable

\*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fooging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pents.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

# PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

# DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist, Wear googles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

# **FIRST AID**

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses. If present, after the first 5 minutes, then continue rinsing eve; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treat-

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may

# DOT SHIPPING NAME

Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, UN3264, PG III

EPA Reg. No.	
EPA Est.	
Patent Number:	

66171-7 66171-TN-001, 66171-CA-001 5,891,922

Batch No:

**Net Contents:** 

165

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Staphylococcus aureus A.T.C.C. 6538
Pseudomonas aeruginosa A.T.C.C. 15442
Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)
Avian Influenza (H3N2)
Escherichia Coli F18
Porcine circovirus Type 2

# HATOMING EGG GANTIZER:

70°F to 110°F The recommended district of the process of the proce



Office of Gary E. Gaumer P.O. Box 17003, Reno, NV 89511 · Bus: (775) 853-9776 · Fax: (775) 853-9212 · email: gegaumer@preserveinc.com

March 20, 2009

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

1 Amendment to add hatching egg directions for use

We have included a highlighted TekTrol label showing prior approval for such claim. In addition, we have highlighted a Synergize label with the proposed changes.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President



# UNTED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 1, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

GARY GAUMER
PRESERVE INTERNATIONAL
PO Box 17003
RENO, NV 89511-

PRODUCT NAME: SYNERGIZE

COMPANY NAME: PRESERVE INTERNATIONAL

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 66171-7 EPA RECEIPT DATE: 03/30/09

SUBJECT: RECEIPT OF AMENDMENT

**DEAR REGISTRANT:** 

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

P. H. Morre
Front End Processing Staff

Information Services Branch

Information Technology & Resources Management Division

APR 2 2009

Mr. Gary E. Gaumer President Preserve International P. O. Box 17003 Reno, NV 89511

Subject:

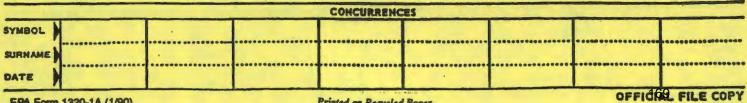
Synergize

EPA Registration Number 66171-7 Your Application Dated: July 24, 2006 EPA Received Data: July 28, 2006

Dear Mr. Gaumer:

This correspondence is intended to correct the Agency comments associated with the stamped accepted label with comments as referenced above. The Agency letter of February 7, 2007 now corrected to read as follows:

In a recent re-review of the data package submitted to the Agency in 2006, it was determined that the recommendation statement was inaccurate regarding the use dilution of the registered product. Briefly, the conclusions statement in the November 2006 review is "the submitted efficacy data (MRID 469088-01) support the use of the product, Synergize, as a disinfectant with virucidal activity against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution". This use dilution was misrepresented in the recommendations section, in the same efficacy review to read that "the proposed label claims that the product, Synergize, is an effective disinfectant against Porcine circovirus type 2 on hard, nonporous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution." The correct dilution, consistent with the efficacy data, is ½ ounce per gallon (1:256).



Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble on (703) 308-6233.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: Amended Efficacy Review dated 4/1/09



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

# April 1, 2009

# **MEMORANDUM**

Subject: Amended Efficacy Review for EPA Reg. No. 66171-7, Synergize

From: Tajah L. Blackburn, Ph.D., Microbiologist

Efficacy Evaluation Team Product Science Branch

Antimicrobials Division (7510P)

Thru: Michele Wingfield, Chief

**Product Science Branch** 

Antimicrobials Division (7510P)

To: Velma Noble PM 31/ Drusilla Copeland

Regulatory Management Branch I Antimicrobials Division (7510P)

Applicant: Preserve International

Reno, NV

Findings: In a recent re-review of the data package submitted to the Agency in

2006, it was determined that the recommendation statement was inaccurate regarding the use dilution of the registered product. Briefly, the conclusions statement in the November 2006 review is "the submitted

efficacy data (MRID 469088-01) support the use of the product, Synergize, as a disinfectant with virucidal activity against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution." This use dilution was misrepresented in the

recommendations section, in the same efficacy review to

read that "the proposed label claims that the product, Synergize, is an effective disinfectant against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution." The correct dilution, consistent with the efficacy data, is ½

ounce per gallon (1:256).



# Synergize, EPA Registration Number 66171-7 Gary E. Gaumer to: Drusilla Copeland

03/23/2009 01:17 PM

Hello,

Thank you for your voicemail.

The issue regarding Synergize, EPA Registration Number 66171-7 is with the February 7, 2007 transmittal letter. In that letter, it is stated: "Synergize is an effective disinfectant against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution."

The correct dilution should be 1/2 ounce per gallon (1:256).

Thank you for your attention.

Gary

775-853-9776



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 25, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-365344

EPA File Symbol or Registration Number: 66171-7

Product Name: SYNERGIZE

EPA Application Receipt Date: 27-Feb-2006 EPA Waiver Request Receipt date: 17-Mar-2006

EPA Company Number: 66171

Company Name: PRESERVE INTERNATIONAL

GARY GAUMER
PRESERVE INTERNATIONAL
PO Box 3135
TURLOCK, CA 95381

SUBJECT: Approval of 100% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 100% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action begins on the date of this letter.

The Action has been identified as Action Code: A57

AMENDMENT; NON-FAST TRACK

If you have any questions, please contact Pesticide Registration Service Fee Ombudsman, at (703) 308-6432.

Sincerely,

Arnold E. Layne, Director

Information Technology & Resources Management Division

# Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. <u>66171-7</u>
Send to SIG: check box  This material is:
<ul> <li>New stamped-accepted label</li> <li>New CSF</li> <li>Notification</li> <li>Final Printed Label</li> <li>Other:</li> </ul>
Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).
Reviewer's Name: Muly Becker
Phone: 308-6359 Division: 10
Date: 3/26/07

read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95 **OPP Identifier Number** Registration **United States Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Manager 1. Company/Product Number 3. Proposed Classification 66171-7 Noble None Restricted 4. Company/Product (Name) PM# Synergize 31 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling Preserve International PO Box 17003 EPA Reg. No. Reno, NV 89511 Check if this is a new address **Product Name** Section - II Final printed labels in repsonse to Amendment - Explain below. February 7, 2007 Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Final labels in response to EPA letter dated, February 7, 2007. Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging Water Soluble Packaging 2. Type of Container Metel Yes Yes Yes Plastic No No Glass Paper If "Yes" No. per If "Yes" No. per Certification must Unit Packaging wgt. container Package wgt Other (Specify) be submitted 4. Size(s) Retail Container 3. Location of Net Contents Information 5. Location of Label Directions Container 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone Nos (include Area Code) Title 530-879-9220 President Gary E. Gaumer 6. Date Application Certification Received I certify that the statements I have made on this form end all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or • • · (Stamped) both under applicable law. .. ••••• 3. Title 2. Signature .... President 5. Date 4. Typed Name

February 22, 2007

Gary E. Gaumer

SYNERGIZE is a multi-purpose disinfectant-cleaner SYNERGIZE provides a broad spec trum kill of gram negative and gram positive microorganisms. SYNERGIZE provides affective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>2</sub>) and performs especially well in areas containing 5%

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethyl ene, polypropylene, PVC (polyvinyl chloride) vinyl, sealed fiberglass, viton, ethylene propylene, nitnle, acrylic and polyurethane

### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed food or litter

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilrties Waterers Feeders, Hauting Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles

### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator extenors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes All surfaces must be rinsed with clean water and allowed to dry before reuse

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse

## **DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:**

- 1) Remove all animals and feed from the premises, vehicles and enclosures
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz SYNERGIZE per gallon of water (1:256), using conventional spraying methods
- 6) Allow all treated areas to remain in contact with this solution for at least 10
- 7)Immerse equipment used in handling and restraining animals, forks, shovels and scrapers used for removing manure in SYNERGIZE at a dilution of 1 256. Allow to remain in contact for at least 10 minutes
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with

# potable water before reuse DIRECTIONS FOR USE IN FARM-PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF, PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses
- 2) Remove all animals and feed from the premises, vehicles, and enclosures
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc from floors surfaces, and from walks to ceiling of barns opens, stalls ochutes and other facilities occupied or traversed by high or other animals
  4) Empty all troughs, racks, and other feeding and watering appliances
- 5) Thoroughly clearwall eurfaces we is soop on detergent and ensewith water
- 6) Thoroughly saturate all surfaces with a solution of 192 oz SYNERGIZE per gallon of water (1 256) using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes



# CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A T C C 6538 Pseudomonas aeruginosa A.T.C C 15442 Salmonella choleraesuis A.T.C.C. 10708 Aspergillus fumigatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS) Avian Influenza (H3N2) Escherichia Coli F18 Porcine circovirus Type 2

# **ACTIVE INGREDIENTS**

Alkyl (C12 67%, C14	25%, C	6 7%, C18	1%) dimethyl	benzyl ammonium chloride
Glutaraldehyde .				
INERT INGREDIENT	rs			
TOTAL				100.00%

# KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATE-**MENTS** 

See First Aid statement and additional precautions on side panel

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

# PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

## CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning If burned, stay out of smoke.

## PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

EPA Registration No.: 66171-7

EPA Establishment No.: 66171-TN-001

66171-CA-001

Patent Number: 5,891,922

## NEPA HAZARD CLASSIFICATION

HEALTH	FIRE	REACTIVITY	SPECIFIC
3	1	1	None

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz SYNERGIZE per callon of water (1 256) Allow to remain in contact for 10 minutes
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry \( \psi \) livestock or employ equipment until treatment has been absorbed, set or died
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and noise with potable water before reuse

### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises trucks coops, and crates
- 2) Remove all litter and droppings from floors walls and surfaces of facilities occupied or traversed by poultry
- 3) Empty all troughs, racks, and other feeding and watening appliances
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried
- 7) Thoroughly scrub treated feed racks troughs, automatic feeders, fountains waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse

Prior to fooging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 100 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gation water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse

\*NOTE: The fog generated is very imitating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

## PRECAUTIONARY STATEMENTS Hazards to humans and domestic animals

### DANGER

KEEP OUT OF REACH OF CHILDREN, Corrosive, Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse

# STATEMENT OF PRACTICAL TREATMENT

# FIRST AID

IF IN EYES: Hold eye open and nose slowly and gently with water for 15-20 minutes, rer contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison trol center or doctor for treatment advice

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes, call a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance. then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control cen ter or doctor for further treatment advice

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice, have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor, do not give anything by mouth to an unconscious person

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA 176

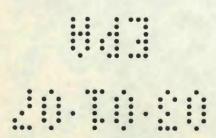


Zephyr Cove, NV 89448 (209) 664-1607 •www preserveinternational com

# SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.



SYNERGIZE is a multi-number disinfertant-cleaner SYNERGIZE provides a broad spec from kill of gram pegaltive and gram positive microorganisms. SYNERGIZE provides effective disinfection and cleaning in one operation. SYNERGIZE is effective in warm soft or hard water (as much as 1000 opm CaCOa) and performs especially well in areas containing 5%

SYNERGIZE is for use on plazed ceramic and tile surfaces, stainless steel, aluminum, chrome galvanzed metal tip brass zinc glass hard non-porous treated wood, polyethyl ene polypropylene PVC (polyvinyl chloride), vinyl sealed fiberglass viton, ethylene propylene, nitrile, acrylic and polyurethane

### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities, Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities Waterers Feeders Hauling Equipment Dressing Plants, Loading Equipment, Farrowing Barns, Nursenes, Blocks, Creep Areas, and Chutes This product is also for use in Farm Premise Foune Facilities Veal Barns Ratite Facilities (Ostrich, Emu and Rhea Facilities). Call Pens and associated Farm Vehicles

### USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator extenors, telephone booths, and garbage cans in non-animal areas associated with the sites noted above Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly Allow surfaces to remain wet for 10 minutes All surfaces must be nosed with clean water and allowed to dry before reuse

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gal-Ion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes Change the disinfecting solution when solution becomes visibly dirty

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or danking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse

# DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures
- 2) Empty all troughs, racks, and other feeding and watering appliances
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hoos
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz SYNERGIZE per gallon of water (1 256), using conventional spraying methods
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes
- 7)Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1 256 Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come inecontactewith fixed with soap or detergent, and rinse with

# potable water before reuse DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES CALF PENS AND VEHICLES: 1) Do not use in milking stalls, milking parlors, or milk houses

- 2) Remove all animals and feed from the premises, vehicles, and enclosures
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of harns, pens, stalls, chutes, and other facilities occupied or traversed by hegs or other admals
  4) Empty all troughs racks, and other feeding and watering appliances
  5) Thoroughly clean all surfaces with soap or detergent and unse with water

- 6) Thorough auturale all surfaces with a solution of 142 oz SYNERGIZE per gation of water (1 256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes



Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Frver, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538 Pseudomonas aeruginosa A.T.C.C. 15442 Salmonella choleraesuis A.T.C.C 10708 Asperoillus furnicatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS) Avian Influenza (H3N2) Escherichia Coli F18 Porcine circovirus Type 2

# **ACTIVE INGREDIENTS**

Alkyl (C12 67%,	C14 25%	, C	. 7%	, C10	1%)	dimeth	yl benzy	I ammonium chlori
								26.00%
Glutaraldehyd	e							7.00%
INERT INGREDI	ENTS							67.00%
TOTAL								

# KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATE-**MENTS** 

See First Aid statement and additional precautions on side panel

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty

# CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

# PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

EPA Registration No.: 66171-7

EPA Establishment No.: 66171-TN-001

66171-CA-001

Patent Number: 5.891.922

### NEPA HAZARD CLASSIFICATION

HEALTH	FIRE	REACTIVITY SPECIFIC		
3	1	1	None	

- 7) Immerse all hallers ropes and other types of equipment used in handling aft." restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz SYNERGIZE per gallon of water (1.256). Allow to remain in contact for 10 minutes
- 8) Ventilate buildings cars hoats coops and other closed spaces. Do not house poultry at livestock or employ equipment until treatment has been absorbed, set or doed
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, foundains, waterers and equipment which may come in contact with food with soap or detergent, and onse with notable water before reuse

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises trucks, coops and crates
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by noultry
- 3) Empty all troughs racks and other feeding and watering appliances
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1 256) for a period of 10 minutes
- 6) Ventilate building coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried,
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders fountains waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse

Prior to fooging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 10 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

\*NOTE: The fog generated is very impating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fooaina. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

# PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

# DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive, Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear googles or face shield, Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N. P. R. or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

### STATEMENT OF PRACTICAL TREATMENT

# FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; reri contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison trol center or doctor for treatment advice

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes, call a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air If person is not breathing, call 911 or an ambulance. then give artificial respiration, preferably by mouth-to-mouth, if possible, call a poison control center or doctor for further treatment advice

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow, do not induce vomiting unless told to do so by the poison control center or doctor, do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastno lavage Measures against circulatory shock, respiratory depression and convulsion may be needed

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA

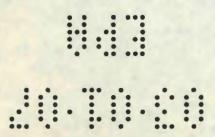


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# SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.



SYNERGIZE is a multi-purpose disinfectant-cleaner SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO3) and performs especially well in areas contaming 5%

serum
SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitnle, acrylic and polyurethane

# **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes, This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1 256) to precleaned surfaces Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes All surfaces must be nosed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

# DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods
- 6) Allow all treated areas to remain in contact with this solution for at least 10
- 7)Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which majecome in contact with food with soap or detergent, and rinse with

# DIRECTIONS FOR 35 IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES PACKLINES CALP PENS AND VEHICLES: 1) Do not use in milking stalls, milking pariors, or milk houses.

- 2) Remove all animals and feed from the premises, vehicles, and enclosures
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to goding of barns, pens, stalls, chartes, and other facilities occupied or trave/sectory sogs or other animals

  4) Empty all troughs, racks, and other feeding and watering appliances.

  5) Thosoughly sleap all surfaces with soap or delergent and rinse with water.

- 6) Thomography saturate all serfaces with a solution of 1/8 oz SYNERGIZE per gallon of water (1 256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes

# SYNERGIZE

# CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas. and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538 Pseudomonas aeruginosa A.T.C C 15442 Salmonella choleraesuis A.T.C.C. 10708 Aspergillus fumigatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS) Avian Influenza (H3N2) Escherichia Coli F18 Porcine circovirus Type 2

# **ACTIVE INGREDIENTS**

Alkyl (C12 67%, C14 25%	, C 4 7%, C 4 1%) dimethyl	benzyl ammonium chloric
*************		
Glutaraldehyde	* * * * * * * * * * * * * * * * * * * *	
INERT INGREDIENTS .		
TOTAL		

# KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATE-**MENTS** 

See First Aid statement and additional precautions on side panel

# STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### **PESTICIDE STORAGE:**

Store away from heat. Do not transfer to another container. Do not reuse empty

## CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

EPA Registration No.: 66171-7

EPA Establishment No.: 66171-TN-001

66171-CA-001

Patent Number: 5,891,922

# NEDA HAZADO CLACCICICATION

	NITA HAZARD CLASSIFICATION					
	HEALTH	FIRE	REACTIVITY	SPECIFIC		
1	3	1	1	None		

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1 256) Allow to remain in contact for 10 minutes
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house positry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes.
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FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

# PRECAUTIONARY STATEMENTS Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN, Corrosive, Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N. P. R. or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse

# STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minute contact lenses, if present, after the first 5 minutes, then continue rinsing eye, call a po trol center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes, call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control cen ter or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow, do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage, Measures against circulatory shock, respiratory depression and convulsion may be needed

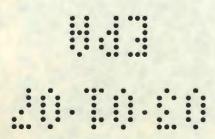
ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA



## SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

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# Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

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Re	eviewer's Name: <u>Dr</u>	usilla	Cof	peland	• · · · · · · · · · · · · · · · · · · ·
Ph	none: 703-308-6224	Divisi	on: _	AD	

Date: 3/1/67

FEB - 7 2007

-Mr. Gary E. Gaumer President Preserve International P. O. Box 17003 Reno, NV 89511

Subject:

**Synergize** 

EPA Registration Number 66171-7 Your Application Dated: July 24, 2006 EPA Received Data: July 28, 2006

## Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with the following comments:

## **Proposed Labeling:**

Add additional organism (Porcine corcovirus type 2 to label)

## **Efficacy Review:**

- 1. The proposed label claims that the product, Synergize, is an effective disinfectant against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution. Data provided supports this claim.
- 2. Make the following changes to the proposed label:
  - a. Under the "Description" section (left panel), change "fiberglass" to read "sealed fiberglass." Fiberglass is a porous surface.
  - b. Under the "Use Directions" section regarding vehicles (left panel), change "course spray" to read "coarse spray."
  - c. Under the list of microorganisms, change "Avian influenza" to read "Avian Influenza virus (H3N2)".



## **Other Comments:**

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

A stamped copy of the label is enclosed for your records.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure:

### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5%

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brase, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### **DIHECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Pouttry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veel Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

### **USE DIRECTIONS:**

and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator riphone booths, and garbage cans in non-animal areas associated with the sites re. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinaed with clean water and allowed to dry before reuse.

SOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or course apray ayetem. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to cellings of barns, pans, stalls, chutes, and other facilities occupied or traversed by hogs
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- equipment used in handling and restraining animals, forks, shovels, and sed for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and aguigment which may come in contact with food with soap or detergent, and rinse with

### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, YEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking pariors, or milk houses.
- 2) Remove all animals and feed from the premises, vahicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rings with water.
- 6) Thoroughly seturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



# SYNERGIZE

## CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilitles: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538 Pseudomonas aeruginosa A.T.C.C. 15442 Salmonella choleraesuis A.T.C.C. 10708 Aspergitus fumigatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS) Avian Influenza Escherichia Coli F18 Porcine circovirus Type 2

#### **ACTIVE INGREDIENTS**

Alkyl (On 67%, On 25%, On 7%, On 1%) dimethyl benzyl ammonium chloride

20.00 A		
Glutaraldehyde		
NERT INGREDIEN	ITS	
TOTAL		

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATE-**MENTS** 

See First Aid statement and additional precautions on side panel

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

#### PESTICIDE STURAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutety nazardous, improper disposal of excess pesticide. spray mocture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. CEPTOT

EPA Registration No.: 66171-75 with COMMENTS EPA Establishment No.: 66171-TNg@PA Letter Dated 66171-CA-001

Patent Number: 5,891,922

HEALTH	FIRE	REACTIVITY	_ SRECIFIC	Federal Insecticide, and Rodenticide Act
***************************************	*****		HAMEDCIGE	SHO KODENDERDE MA
3	1	1	ambuned	for the pertiside
				under EPA Reg. No.

Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com L 6 17 1 - 7

- 7) immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:258). Allow to remain in
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly acrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FOULTRY GOOSE. 1) Remove all poultry and feets from premises, tracks, coopeans crass.

- 2) Remove all litter and afoppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- Thoroughly clean all surfaces with soap or detergent and rinse with water.
- Saturate surfaces with 1/2 ounce SYMERGIZE per gallon water (dilute1 256) for a
- Vertilate building, coops, and other blose spaces. Do not house pouttry or employ equipment until treatment has been absorbed, set, or died.
- 7) Thoroughly scrub treated feed racks troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 ouble feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, autometic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse

"NOTE: The log generated is very irritating to eyes, skin, and mucous membranes. Under no circurretances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSHAMSHA, goggles, long sleeves and long

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE BURFACES.

#### PRECAUTIONARY STATEMENTS Hazerds to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN, Corrosive, Causes irreversible eve damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on ciothing. Do not breathe apray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N. P. R. or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some Individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the tollet. Remove contaminated clothing and wash before reuse.

### STATEMENT OF PRACTICAL TREATMENT

If In EYEM; Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, it present, after the first 5 minutes, then continue rinsing eye; call a poison con trol center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control cen ter or doctor for further treatment advice.

tr' SWALLUWEU; Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconecious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, med ical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage Measures against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge affluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

A1-A @ A	110 0-11
Net Contente:	U.S. Gallons

Batch No.	
-----------	--

## SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*NOTE: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

## WASHINGTON, D.C. 20460

## **MEMORANDUM**

DATE:

November 16, 2006

OFFICE OF PREVENTION, PESTICIDES AND

TOXIC SUBSTANCES

SUBJECT:

Secondary Review of Contractor's (DynCorp Systems & Solutions LLC)

Efficacy Review for Synergize;

EPA Reg. No. 66171-7; DP Barcode: D332344

FROM:

Lorilyn M. Montford & mm 11/16/06

Efficacy Evaluation Team

Antimicrobials Division (7510P)

THRU:

Dr. Tajah Blackburn, Ph.D., Acting Team Leader

Efficacy Evaluation Team

Antimicrobials Division (7510P)

TO:

Velma Noble, PM 31/Drusilla Copeland

Regulatory Management Branch I Antimicrobials Division (7510P)

APPLICANT:

Preserve International

Reno, NV

## FORMULATION FROM LABEL:

Active Ingredient(s)	<u>% by wt.</u>
Alkyl (C <sub>12</sub> 67%, C <sub>14</sub> 25%, C <sub>16</sub> 7%, C <sub>18</sub> 1%)	
dimethyl benzyl ammonium chloride	26%
Glutaraldehyde	
INERT INGREDIENTS	
Total	

### I BACKGROUND

The product, Synergize (EPA Reg. No. 66171-7), is an EPA-approved disinfectant (bactericide, virucide, fungicide) for use on hard, non-porous surfaces in farming and animal care environments. The label claims that the product is effective in the presence of 1000 ppm hard water and a 5% organic soil load. The applicant requested to amend the registration of this product to add claims for effectiveness as a disinfectant against Porcine circovirus type 2. The study was conducted at MicroBioTest, Inc., located at 105 Carpenter Drive in Sterling, VA 20164.

This data package contained a letter from the applicant to the Agency (dated July 24, 2006), one study (MRID No. 469088-01), a Statement of No Data Confidentiality Claims for this study, and the proposed label.

## II USE DIRECTIONS

The product is designed for use in disinfecting hard, non-porous surfaces such as appliance exteriors, equipment (e.g., feeders, hauling equipment, loading equipment, waterers), floors, garbage cans, sinks, tables, telephone booths, and walls. The proposed label indicates that the product may be used on hard, non-porous surfaces including: fiberglass, glass, glazed ceramic, glazed tiles, metal (e.g., aluminum, brass, chrome, galvanized metal, stainless steel, tin), plastic (e.g., acrylic, polyethylene, polypropylene, polyvinyl chloride, vinyl), and treated wood. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Pre-clean surfaces. Prepare a use solution by adding 0.5 ounce of the product to 1 gallon of water (a 1:256 dilution). Apply the use solution with a cloth, sponge, mop, or mechanical coarse spray device until surfaces are thoroughly wet. Treated surfaces must remain wet for 10 minutes. Rinse with clean water. Allow to air dry. Food contact surfaces must be scrubbed with soap or detergent and rinsed with potable water prior to use.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

### Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10<sup>4</sup> from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per

each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

## Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level. These Agency standards are also presented in DIS/TSS-2.

## V COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 469088-01 "Virucidal Effectiveness Test, Post weaning multisystemic wasting syndrome (Porcine circovirus type 2)" for Synergize, by Lauren A. Blaszak. Study conducted at MicroBioTest, Inc. Study completion date – July 18, 2006. Laboratory Project Identification Number 366-107.

This study was conducted against Porcine circovirus type 2 (obtained from American BioResearch Laboratories) using cultures of PT-1 cells (obtained from American BioResearch Laboratories) as the host system. Two lots (Lot Nos. 33458 and 33519) of the product, Synergize, were tested according to MicroBioTest Protocol "Virucidal Effectiveness Test, Post weaning multisystemic wasting syndrome (Porcine circovirus type 2)," dated May 9, 2006 (copy provided). A use solution was prepared by adding 1 mL of the product to 255 mL of 1000±2.9% ppm AOAC synthetic hard water (titration results not provided; a 1:256 dilution). The stock virus culture contained at least a 5% organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried at ambient temperatures. Each virus film was treated with 2.0 mL of the use solution for 10 minutes at 23°C. After the contact period, the virus-disinfectant mixture was neutralized with 2.0 mL of fetal bovine serum containing 0.3% glycine. The plates were scraped with a cell scraper to re-suspend the contents. Ten-fold serial dilutions were prepared, using RPMI 1640 containing 5% fetal bovine serum. PT-1 cells were inoculated in quadruplicate with an unspecified amount of each dilution. The cultures were incubated for 5-7 days at 36±2°C in 5±1% CO<sub>2</sub>. The plates were assayed by an immunofluorescence assay. Controls included those for plate recovery, cytotoxicity, cytotoxicity-related viral interference, cell viability/sterility, and neutralizer effectiveness. The 50% fluorescent focus forming unit dose per mL (FFFUD<sub>50</sub>/mL) was determined using the method of Reed and Muench.

### V RESULTS

MRID	Organism		Plate Recovery		
Number			Lot No.	Lot No.	Control
			33458	33519	(FFFUD <sub>50</sub> /mL)
469088-01	Porcine	10 <sup>-2</sup> dilution	Cytotoxicity	Cytotoxicity	10 <sup>5.50</sup>
	circovirus type 2	$10^{-3}$ to $10^{-7}$	Complete	Complete	
		dilutions	inactivation	inactivation	
		FFFUD <sub>50</sub> /mL	$\leq 10^{2.50}$	$\leq 10^{2.50}$	
		Log	$\geq 10^{3.00}$	$\geq 10^{3.00}$	
		reduction			

### VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 469088-01) support the use of the product, Synergize, as a disinfectant with virucidal activity against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1:256 dilution. A recoverable virus titer of at least 10<sup>4</sup> was achieved. Cytotoxicity was observed in the 10<sup>-2</sup> dilutions. Complete inactivation was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level.

## VII RECOMMENDATIONS

- 1. The proposed label claims that the product, Synergize, is an effective disinfectant against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution. Data provided by the applicant support this claim.
- 2. Making the following changes would improve the proposed label:
  - Under the "Description" section (left panel), change "fiberglass" to read "sealed fiberglass." Fiberglass is a porous surface.
  - Under the "Use Directions" section regarding vehicles (left panel), change "course spray" to read "coarse spray."
  - Under the list of microorganisms, change "Avian influenza" to read "Avian influenza virus (H3N2)."



## DATA PACKAGE BEAN SHEET

**Decision #: 369573** 

DP #: (332344)

Date: 07-Sep-2006 Page 1 of 1

## \* \* \* Registration Information \* \* \*

Company.	66171 - PRESERVE I	NTERNATIONAL		
Risk Manager:	RM 31 - Velma Noble	- (703) 308-6233 Room# PY1	S-8219	
k Manager Reviewer:	Drusilla Copeland DC	COPELAN		<del>-</del>
Sent Date:		Calculated Due Date	1	Edited Due Date:
Type of Registration:	Product Registration -	Section 3	OK.	
Action Desc:	(A57) AMENDMENT;	NON-FAST TRACK;	XI	
Ingredients:	043901, Glutaraldehy	de(7%)		
	069175, Alkyl* dimeth	nyl benzyl ammonium chloride "	(67%C12, 25%C1	4, 7%C16, 1%C18)(26%)
	*	* * Data Package In	formation *	**
Expedite:	○ Yes ● No	Date Ser	t: 07-Sep-2006	Due Back:
DP Ingredient:	043901, Glutaraldehy	de		
	069175, Alkyl* dimeth	nyl benzyl ammonium chloride	(67%C12, 25%C1	4, 7%C16, 1%C18)
DP Title:				
		Label Included: Yes	No Parer	nt DP #:
CSF Included:	○ Yes ● No			nt DP #:
	○ Yes ● No	Label Included: Yes	No Parer	
CSF Included:	Yes ● No			Last Possible Science Due Date: 16-Nov-2006
CSF Included:	Yes ● No			
CSF Included:  Assigned T  Organization: AD / F  Team Name: EET	Yes ● No			Last Possible Science Due Date: 16-Nov-2006
CSF Included:  Assigned T  Organization: AD / F  Team Name: EET	Yes No			Last Possible Science Due Date: 16-Nov-2006 Science Due Date: 10/2/06
CSF Included:  Assigned T  Organization: AD / F  Team Name: EET  eviewer Name:	Yes No		Date Out	Last Possible Science Due Date: 16-Nov-2006 Science Due Date: 10/2/06

\* \* \* Additional Data Package for this Decision \* \* \*

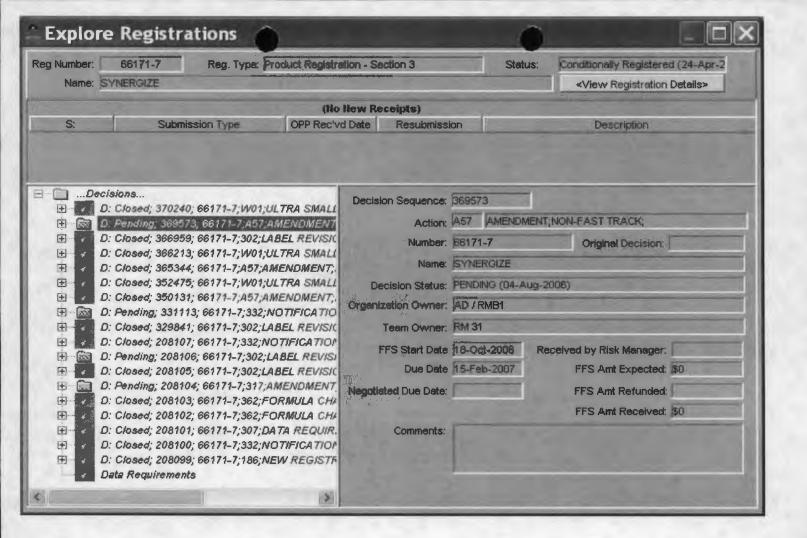
No Additional Data Packages

\* \* \* Data Package Instructions \* \* \*

Please review MRID #469088-01, Label

Dyn Corp: need back by 10/20/06

I received this data package on 10/26/06 /money





United States

## **Environmental Protection Agency**

	Registration
×	Amendment
	Other

OPP Identifier Number

	shington, DC 204			Other	ment	
	Application	on for Pestic	de - Sectio	n I		
1. Company/Product Number 66171 - 7		2. EPA Nobl	Product Manage	or	3. Pr	posed Classification
4. Company/Product (Name) SYNERGIZE		PM# 32				
5. Name and Address of Applicant (Include ZIP) Preserve International PO Box 17003 Reno, NV 89511  ** Check if this is a new address	Code)	(b)(i), i to: EPA	ny product is s Reg. No	similar or iden	tical in co	FIFRA Section 3(c)(3) mposition and labeling
		Section -	11			
Amendment - Explain below.  Resubmission in response to Agency let  Notification - Explain below.	tter dated		Final printed la Agency letter "Me Too" App Other - Explain	dication.	se to	
Explanation: Use additional page(s) if neces  Addition of Porcine circovirus type		1.				
	HALD COME TO SECURE THE TAIL	Section -	H		SAMA TENENSISSE	
1. Material This Product Will Be Packaged In:  Child-Resistant Packaging  Yes  No  * Certification must be submitted  1. Waterial This Product Will Be Packaged In:  Unit Packaging  Yes  No  If "Yes" Unit Packaging waterial	No. per	Water Soluble I Yes No If "Yes" Package wgt	No. per container	2. Type of	Container  Metal Plastic Glass Paper Other (S	pecify)
3. Location of Net Contents Information  Label Container	4. Size(s) Ret	tail Container	5.	Location of La	bel Directio	ns
6. Manner in Which Label is Affixed to Product	Lithog Paper Stenci	raph glued iled	Other _			
		Section - I	V			• • • •
1. Contact Point   Complete items directly below	w for identificatio	n of individual to b Title President	e contacted, if n	ecessary, to p		No gnolude Area Code)
f certify that the statements I have made I acknowledge that any knowlingly false both under applicable law.		all attachments th			t or •	6. Date Application Received  *(Stamped)
2. Signature		3. Title President			٠	••••
4. Typed Name Gary E. Gaumer		5. Date July 24, 2006				•



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 16, 2006

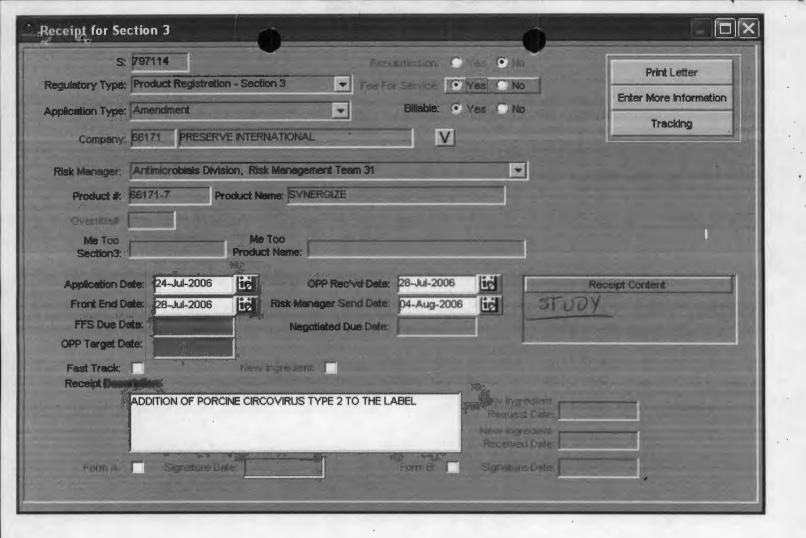
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRESERVE INTERNATIONAL PO Box 3135 TURLOCK, CA 95381

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 28-JUL-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.





Office of Gary E. Gaumer P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 853-9212 • email: gegaumer@preserveinc.com

July 24, 2006

Ms. Velma Noble
Office of Pesticides Programs (7504C)
United States Environmental Protection Agency (AMEND)
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

## 46908801

1 Amendment to add Porcine circovirus type 2 to the label.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,

Preserve International

Gary E. Gaumer

President



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 4, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

### PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-369573

EPA File Symbol or Registration Number: 66171-7

Product Name: SYNERGIZE EPA Receipt Date: 28-Jul-2006 EPA Company Number: 66171

Company Name: PRESERVE INTERNATIONAL

GARY GAUMER
PRESERVE INTERNATIONAL
PO Box 3135
TURLOCK, CA 95381

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

## Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A57

AMENDMENT; NON-FAST TRACK;

Please remit payment in the amount of: \$ 3,150 to:

By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251 By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277 Pittsburgh, PA 15251-6277

Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is soley associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency 1200 Pennsylvania Ave NW Washington, DC 20460 By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-6432.

Sincerely.

Front End Processing Staff

Information Technology & Resources Management Division

# Fee for Service



This package includes the following	for Division
New Registration  • Amendment  Studies?  Fee Waiver?  volpay % Reduction:	AD BPPD RD Risk Mgr. 31
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	797114 66171-7 7/28/2006
☐ This item is NOT subject to F	FFS action.
Action Code:	Parent/Child Decisions:
Requested:  Granted:  Amount Due: \$	
Reviewer: P. Jenkins Remarks:	Date: <u>8- 2- 0</u> ∕ <u></u>

## Material to be added to an e-Jacket

Reg. No. 46171-7
1. Placement within the e-Jacket:
Default: chronological top  Other: (PDF page number, i.e., "before page 45")
2. Is this material:  Newly stamped accepted label  Notification New CSF Final Printed Label  Other:
3. Attach this notice on top of the material. It must be clipped all together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room 230).
Reviewer's Name: MMS/CAD
Phone: 308-0107 Division: 40
$\bigcap_{i=1}^{n} \gamma_{i}$



## NITED STATES ENVIRONMENTAL PROTECTION AGENCY Washington, D.C. 20460

JUL 1 0 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Gary E. Gaumer President Preserve International P.O. Box 3135 Turlock, CA 95381

Subject:

Synergize

EPA Registration No.66171-7

Amendment Dated: March 30, 2006 EPA Received Date: March 11, 2006

Dear Gary E. Gaumer

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, is acceptable.

## **Proposed Amendment**

Revised Label Adding Fogging Directions

## **General Comments**

A stamped copy of the accepted label is enclosed for your records. Submit (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely

Product Manager (31)

Regulatory Management Branch1

	SURNAME N NAME (	
EPA Form 1320-1A (1/90)  Pristed on Recycled Ponce  OFFICIAL FILE COPY		

DESCRIPTION SYNERGIZE is a multi-purpose disinfectant-cleaner SY frum kill of gram negative and gram positive microorge Ilve disinfecting and clearing in one operation. SYNER water (as much as 1000 ppm CaCC<sub>3</sub>) and performs SYNERGIZE is for use on glazed ceramic and chrome, galvanized metal, lin, brass, zirc, glass ene, polypropylene pvc (polyvinyl chlorde) nitrile, acrylic and polyurethane DIRECTIONS FOR USE: It is in violation of Federal Law to use this Registered for disinfecting and cleaning SYNERGIZE cleaner-disinfectant following Animal and Poultry House Hatcheries and Swine Producing ities. Waterers. Faeders, Ha Farrowing Barris, Murseries in Farm Premise, Equine Facilities). Call Pens 2 USE DIRECTIO To disinfect and . exteriors, telep

NERGIZE provides a brown nisms SYNERGIZE provides GIZE is effective in warm, soft or hard especially well in areas containing 5%

tile surfaces stainless steel aluminum. hard non-porous treated wood, polyethylvinyl, fiberglass, viton, ethylene propylene,

product in a manner inconsistent with its labeling hard non-porous surfaces. Not for use on feed, food

is specifically formulated for industrial use in the ing facilities Turkey, Breeder, Grow Out, Fryer, Layer, Facilities as well as the following equipment in these facilling Equipment, Dressing Plants, Loading Equipment, ks. Creep Areas, and Chutes. This product is also for use des, Veal Barns, Ratte Facilities (Ostrich, Emu and Rhea acciated Farm Vehicles.

fean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator one booths, and parbage cans in non-animal areas associated with the sites Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to faces. Apply with cloth, sponge, mop or mechanical coarse spray device, surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. faces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or course spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalts, chutes, and other facilities occupied or traversed by hogs
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10
- 7)Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain r at least 10 minutes
- aldings, and other closed spaces. Do not house swine or other livestock until has been absorbed, set, or dried.
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with

DIRECTIONS FOR USE IN FARM PREMISES, BOUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PERS AND VEHICLES:

- 1) Do not use in milking stalls, milking periors, or milk neues
- 2) Remove all animals and feed from the premises, vehicles, and enclosures
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- Empty all troughs, facks, and other feeding and watering applicaces
   Thoroughly clean all surfaces with apap or deterging and rinse with water.
- Thoroughly saturate all surfaces with a solution of 1/2 oz. SWNERGIZE per gallon of water (1 256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes



# YNERGIZE

## LEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C 6538 Pseudomonas aeruginosa A.T.C.C. 15442 Salmonefia choleraesuis A.T.C.C. 10708 Aspergillus fumigatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS)

#### **ACTIVE INGREDIENTS**

Alkyl (Cu 87%, Cu 25%, Cu 7%, Cu 1%) dimethyl benzyl ammonium chloride 26.00% 

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATE-**MENTS** 

See First Aid statement and additional precautions on side panel

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance

EPA Registration No.: 66171-7 EPA Establishment No.: 66171-TN-M1C CFPTED

Patent Number: 5,891,922

NFPA HAZARD CLASSIFICATION FIRE REACTIVITY S. ECH HEALTH Motenticide Act as amended, for the pesticide, registered under Zephyr Cove, NV 89448 (209) 664-1607 •www.preserveinternational.com EPA Reg. No. 66171

7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing markers in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in

8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dired.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

1) Remove all poultry and feeds from premises, trucks, coops, and crates.

- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry
- 3) Empty all troughs, racks, and other feeding and watering appliances
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1 256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before rause

\*NOTE: The tog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

#### PRECAUTIONARY STATEMENTS Hazards to humans and domestic animals

KEEP OUT OF REACH OF CHILDREN, Corrosive Causes irreversible eve damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear googles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N. P. R. or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

#### STATEMENT OF PRACTICAL TREATMENT

#### FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remov. contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing, rinse skin immediately with wenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378

OTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage Measures against circulatory shock, respiratory depression and convulsion may be needed

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuanes, oceans or other water amiess in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA

Net Contents:

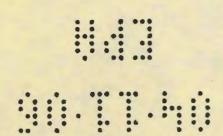
US Gallons

Batch No

## SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment (less time if area is well ventilated).

\*N E: The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.



#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, act or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5%

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, gelvanized metal, tin, brase, zinc, glass, hard non-porous treated wood, polyethyl-ene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene. nitrile, scrylic and polyurethane.

#### **DIRECTIONS FOR USE:**

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Aremel and Poultry Housing facilities: Turkey, Breader, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loeding Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veel Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### **USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of wells, floors, tables, sinks, refrigerator denors, telephone booths and garbage cans in non-animal areas associated with the sites oted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:255) to precisened surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be nosed with clean water and allowed to dry before reuse.

SOOT/SHOE WASH: To prevent tracking harmful organisms into enimal areas, shoe beths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per galion water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or course apray systerm. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all enimals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, apider webs, etc. from walls to ceilings of bams, pens, stalls, chutes, and other facilities occupied or traversed by hogs
- 4) Thoroughly clean all surfaces with soap or detergent and nose with water
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional agraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10
- 79mmerse equipment used in handling and restraining animals, fortes shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 3) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9)Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with notable water before ruse

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNS, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, menure, caked on dirt, soider webs, etc. from floors, surfaces, and from walls to colling of barns, pens, staffs, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional epraying methods. Allow to remain in contact with this solution for at least 10 minutes.

PRESERVE

CYNERGIZE CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facil-Ities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Ferrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities). Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538 Pseudomonas aeruginose A.T.C.C. 15442 Salmonella choleraesuis A.T.C.C. 10708 Aspergillus furrigatus A.T.C.C. 36607 Porcine Respiratory & Reproductive Syndrome Virus (PRRS)

#### **ACTIVE INGREDIENTS**

Alleyl (Ca 67%, Cu 25%, Cu 7%, Cu 1%) dimethyl benzyl ammonium chloride 26.00*	%
Citytaraldahyda	%
INERT INGREDIENTS	6
TOTAL100.00	%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS See First Aid statement and additional precautions on side panel

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal. PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke

PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous Improper disposar of the perpendicular spray mixture, or rinsate is a violation of Federal Izw. If their wastes cannot be spray mixture, or rinsate is a violation of Federal Izw. If their wastes cannot be or Environmental Control Agency or the Hazardeus Waster egress nearest EPA Regional Office for guidance

EPA Registration No.: 66170 EPA Establishment Short 6 Patent Number: 5,597,922

NFPA HAZAGE STASSIFIC

REACTIVITY HEALTH

Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining aremals, as well as forks, shovels and sorapers used for removing menure in a solution of 1/2 oz. SYNERGIZE per gation of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried
- 9) Thoroughly acrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rines with potable water before reuse.

### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with some or determent and ringe with water
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute1:256) for a period of 10 minutes
- Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and nose with notable water hefore rause.

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog dealred areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 cunce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before rause.

"NOTE: The log generated is very irritating to eyes, skin, and mucous membranes. Under no circurretences should a room or building be entered by snyone within two hours of the actual fooging. If the building or room must be entered, then the individuals entering the building must weer a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long

FORGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

#### PRECAUTIONARY STATEMENTS Hazards to humans and domestic animals

#### DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin hums. May be fatel it inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Weer a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the tollet. Remove contaminated clothing and wash before reuse.

#### STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses. If present, after the first 5 minutes, then continue rinsing eye; call a poison controi center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take of contempated clothing; rinse skin immediately with plenty of water for 15-20 minutes, call a poison control center or doctor for treatment advice.

IF MOHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison contro. ter or doctor for further treatment advice

E-SWALLOWED: Call a poison control center or doctor immediately for treatment advice; have ein a glass of water if able to swallow, do not induce vorniting unless told to do so by the control center or doctor; do not give anything by mouth to an unconscious person.

To TA ME NUMBER: Have the product container or label with you when calling a poison control co Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastno lavage Measures against circulatory shock, respiratory depression and convulsion may be needed

ENVIRONMENTAL MAZARDS: This product is toxic to fish. Do not apply directly to water Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, esquaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local savege treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

Net Contents:

U.S. Gallons

Batch No .:

SEPA Environmental I	red States Protection Age ton, DC 20460	ncy		tration idment	OPP Identifier Number
A	pplication for l	Pesticide - Sec	tion I		-
1. Company/Product Number 66171-7		2. EPA Product Ma	neger	3, F	Proposed Classification
4. Company/Product (Name) SYNERGIZE		PM# 31			None Restricted
5. Name and Address of Applicant (Include ZIP Code Preserve International PO Box 3135 Turlock, CA 95381 Check if this is a new address			is similar or id	entical in c	h FIFRA Section 3(c)(3) omposition and labeling
	Sec	tion - II			
Resubmission in response to Agency letter de Notification - Explain below.  Explanation: Use additionel page(s) if necessary.  The addition of Thermofogging directions.		Agency let "Me Too" Other - Ex	ed labels in repse iter dated Application. plain below.	onse to	
	Sect	ion - III			
1. Material This Product Will Be Packaged In:					
	No. per container Packag			of Containe  Metal Plastic Glass Paper Other (	Specify)
	Size(s) Retail Contein	ner	5. Location of	Label Directi	ons
3. Manner in Which Lebel is Affixed to Product	Lithograph Paper glued Stenciled	Othe			
		on - IV			
. Contact Point (Complete items directly below for	dentification of indivi	dual to be contacted,	if necessary, to	process this	applications
Name Gary E. Gaumer	Title Presiden	t			ne No. (Include Area Code) -9220 77 5853-97
I certify that the statements I have made on this I acknowledge that any knowlingly false or mis both under applicable law.	leading statement mu	y be punisheble by fi			6. Date Application george (Scamped)
Typed Name	President 5. Date				

Gary E. Gaumer

March 30, 2006

FORA

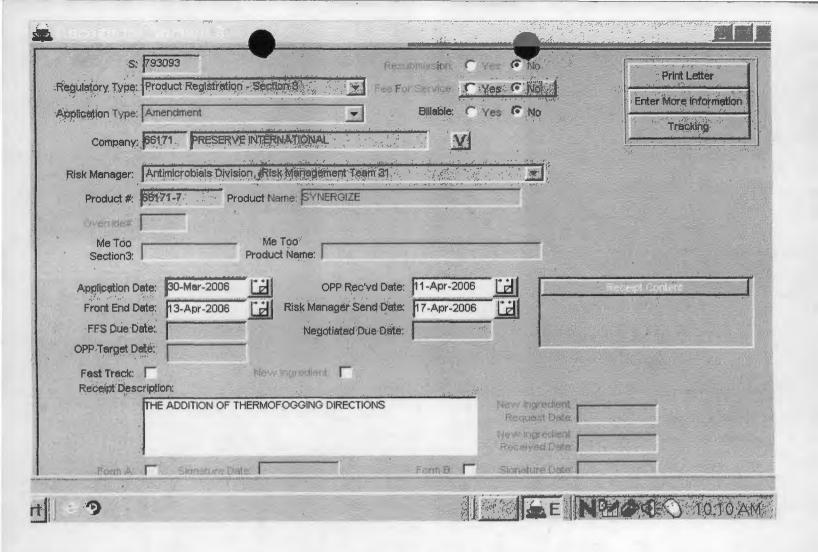
7-10-06

# TASK ASSIGNMENT FORM Antimicrobial Division/Regulatory Management Branch II

A		Completed	by Product	Manag	er	and the second second second	man backman
PRODUCT REVIEWER:	)emitrus				RMB_	I TEAR	<b>4</b>
Description of Action:	Inhelser,	Level .		and granter or the		e Symbol/Reg No	
Decision No. 366959	Submission No	.7930	93	Fee for	Service Action	Code:	
FQPA Action Code: 302	Non-FQPA	Action Code:		Fe	e for Service Fe	er S	
			TEDAY IS		Action 1		
APPLICATION DATE	3		30	1		2005	
EPAPIN DATE		1	11			2005	
REVIEWER ASSIGNED DATE			Salari .			2005	9 5 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9
DATE DUE FROM SCIENCE					* .	2005	
DATE DUE TOPM		1 50.				2005	
Type of Data: PSB Product Ghemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environment	, 6y <sup>47</sup> sea	RASSB Ecological Effects	RASSE Chronic Toxicology	RASSB Exposure

Inhelment - he to Demiting

ATTACHMENTS LEASELING	ELECTED AND ELECTRICAL SECTION OF THE PARTY
8 Part San	Areac Slope Contract Only
Contractor: Arch Slope	Contract No. 0331
Draft Task: Signature	Final Task: Signature 207





## WASHINGTON, D.C. 20460

April 17, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

GARY GAUMER
PRESERVE INTERNATIONAL
PO Box 3135
TURLOCK, CA 95381

PRODUCT NAME: SYNERGIZE

COMPANY NAME: PRESERVE INTERNATIONAL

EPA FILE SYMBOL: 66171-7 EPA RECEIPT DATE: 04/11/06

SUBJECT: RECEIPT OF AMENDMENT

**DEAR REGISTRANT:** 

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

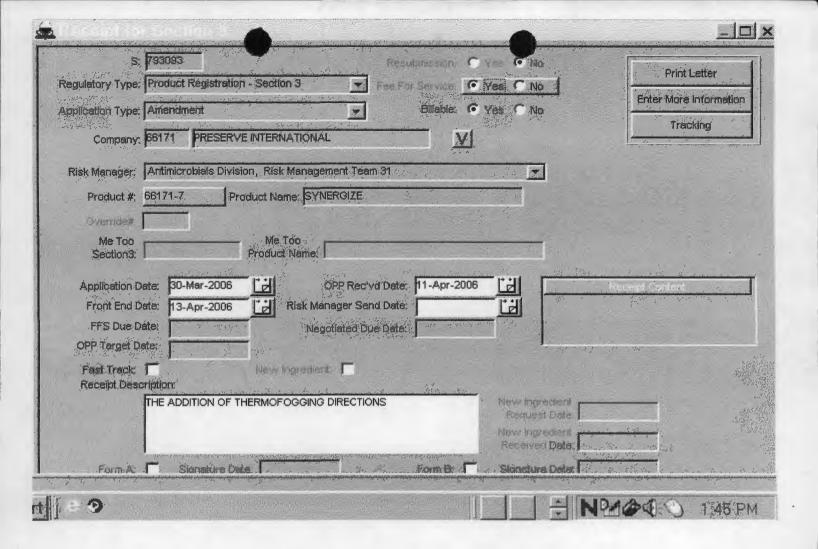
If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 308-6233.

Sincerely,

Front End Processing Staff

Information Services Branch

Information Technology & Resources Management Division



# Fee for Service





This package includes the following	for Division
<ul><li>New Registration</li><li>Amendment</li></ul>	● AD ○ BPPD ○ RD
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 31
Receipt No. S-	793093
EPA File Symbol/Reg. No.	66171-7
Pin-Punch Date:	4/11/06
This item is NOT subject to	FFS action.
Action Code:	Parent/Child Decisions:
Requested:	
Granted:	
Amount Due: \$	
Human Studies:	Cite-All Selective Support
Tox (excluding Six-Pack)	
Other Human Research (efficacy, exposure	e, etc.)
Reviewer: Z. Jones D. William	Date: 4 14 06
Remarks:	